(1)

AD__________

WORKSHOP ON RESEARCH NEEDS IN ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY

Final Report

Kenneth Dickson

June 30, 1988

Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701-5012

Grant No. DAMD17-87-G-7028

Institute of Applied Science
North Texas State University
P.O. Box 13078 NT Station
Denton, Texas 76208

DOD DISTRIBUTION STATEMENT

Approved for public release; distribution unlimited

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1a. REPORT SECURITY CLASSIFICATION Unclassified	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION / AVAILABILITY OF REPORT Approved for public release; distribution unlimited
2b. DECLASSIFICATION / DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S)	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION North Texas State University 6b. OFFICE SYMBOL (If applicable)	7a. NAME OF MONITORING ORGANIZATION
6c. ADDRESS (City, State, and ZIP Code) Institute of Applied Science P.O. Box 13078 NT Station Denton, Texas 76208	7b. ADDRESS (City, State, and ZIP Code)
8a. NAME OF FUNDING/SPONSORING ORGANIZATION U.S. Army Medical Research & Development Command 8b. OFFICE SYMBOL (If applicable)	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER Grant No. DAMD17-87-G-7028
8c. ADDRESS (City, State, and ZIP Code) Fort Detrick Frederick, Maryland 21701-5012	10. SOURCE OF FUNDING NUMBERS

PROGRAM ELEMENT NO.	PROJECT NO.	TASK NO.	WORK UNIT ACCESSION NO.
---	---	---	---

11. TITLE (Include Security Classification)
WORKSHOP ON RESEARCH NEEDS IN ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY

12. PERSONAL AUTHOR(S)
Kenneth Dickson

13a. TYPE OF REPORT	13b. TIME COVERED	14. DATE OF REPORT (Year, Month, Day)	15. PAGE COUNT
Final Report	FROM 6/15/87 TO 6/30/88	1988 June 30	

16. SUPPLEMENTARY NOTATION
Subtitle: Research Priorities in Environmental Risk Assessment
Workshop held August 16-21, 1987, Breckenridge, Colorado

17. COSATI CODES

FIELD	GROUP	SUB-GROUP
--	--	
--	--	

18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
Conference, RA III

19. ABSTRACT (Continue on reverse if necessary and identify by block number)

20. DISTRIBUTION / AVAILABILITY OF ABSTRACT
☐ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT. ☐ DTIC USERS

21. ABSTRACT SECURITY CLASSIFICATION

22a. NAME OF RESPONSIBLE INDIVIDUAL	22b. TELEPHONE (Include Area Code)	22c. OFFICE SYMBOL
Mrs. Virginia M. Miller	301/663-7325	SGRD-RMI-S

Research Priorities in Environmental Risk Assessment

SETAC

WORKSHOP REPORT

SOCIETY OF ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY

Research Priorities in Environmental Risk Assessment

August 16-21, 1987

Breckenridge, Colorado

Edited by:

James A. Fava

William J. Adams

Robert J. Larson

Gary W. Dickson

Kenneth L. Dickson

William E. Bishop

Sponsored by:

U.S. Army Medical Research and Development Command

U.S. Army Chemical Research Development and Engineering Center

The Procter and Gamble Company

The National Agricultural Chemicals Association

Dow Chemical Company

U.S. Environmental Protection Agency

To: Dr. Kenneth L. Dickson
President, Society of Environmental Toxicology and Chemistry

It is our pleasure to submit to you this report, "Research Priorities in Environmental Risk Assessment." In accordance with SETAC's goal of providing a forum for communication among professionals involved with the use, protection, and management of the environment, the Society's Technical and Governmental Affairs Committees organized a workshop, "Consensus Research Needs and Priorities in Environmental Risk Assessment" to identify the research needed to enhance capabilities for conducting environmental risk assessments.

We believe that local, national, and global environmental problems can best be addressed by utilizing the environmental risk assessment approach. The research program outlined in this report will significantly enhance the scientific foundation of the risk assessment process, making it possible to establish environmental priorities on the basis of comparative risk and to allocate limited resources to address the problems of greatest risk.

This report represents the consensus recommendation of more than 40 experts from a wide variety of disciplines representing a cross-section of the Society membership—academia, governmental agencies, public-interest groups, and industry. We therefore believe that this report reflects the best judgment of the scientific community at large. As such, it provides the basis for planning, budgeting, and expanding an initiative for environmental risk assessment research during the next several years.

We are pleased to acknowledge the significant efforts of the many workshop participants who contributed to the development of this report. Thanks are also due to the governmental agencies, associations, and industrial organizations that generously supported the workshop. In addition, we are grateful to Marveen Fishman and Julie Rieser of Battelle Columbus Division and Martina Bianchini of the Monsanto Company for their excellent logistical support, and to Karl Nehring of Battelle Columbus Division for his outstanding editorial assistance.

On behalf of the workshop participants, we hope that this report will be useful in guiding environmental risk assessment research during the next decade.

Respectfully submitted,

William J. Adams
William J. Adams
Chair, Governmental Affairs Committee

James A. Fava
James A. Fava
Chair, Technical Committee

EXECUTIVE SUMMARY

RESEARCH PRIORITIES IN ENVIRONMENTAL RISK ASSESSMENT—A SETAC WORKSHOP

Nature and Scope

The environmental issues facing society today are the most critical in our nation's history. Difficult decisions must be made about potentially expensive solutions to environmental problems. Environmental risk assessment will provide the information necessary to ensure that the best decisions are made. Environmental risk assessment is the most efficient, technically sound, and cost-effective approach to providing the information required to make these decisions. However, research is urgently needed to enhance the use of environmental risk assessment.

Environmental risk assessment integrates knowledge concerning the possible effects of proposed actions that expose plants, animals, and ecosystems to pollutants or stresses in air, water, and soil. The formal scientific techniques used in risk assessment take into account the uncertainty associated with knowledge about effects on the environment and estimate the probability of an identified risk being realized in the environment as a result of a contemplated action. Risk assessment provides technical input to risk management, the process of making decisions about the acceptability of risks and the need for risk reduction.

The Society of Environmental Toxicology and Chemistry (SETAC) recognizes the value of environmental risk assessment in evaluating the extent and magnitude of environmental problems, maximizing options for solving these problems through early detection, in evaluating the efficacy of alternative remedial actions, and in prioritizing and allocating limited research resources.

As a result of this recognition, SETAC convened a workshop involving 40 scientists representing governmental organizations, universities, public-interest groups, industry, and contract research laboratories to identify the research needed to enhance the development of environmental risk assessment strategies and methods.

Objectives and Context

The charge given to workshop participants was to identify technical research needs that would best improve the use and understanding of environmental risk assessment. Current research programs, while achieving substantial advances in knowledge and understanding, do not adequately address the issues necessary to enhance the use of environmental risk assessment in solving key environmental problems such as:

- ecological impacts of improper disposal of hazardous wastes;
- contamination of groundwater and surface water;
- impacts of genetically-altered organisms on the environment;
- effects of municipal and industrial wastewater effluents on aquatic ecosystems;
- air pollution impacts on forest resources;
- destruction of wetland ecosystems; and
- effects of rapid population growth and population shifts to coastal areas on fisheries, shoreline stability, and other considerations.

Improved risk assessment techniques are important in striking a balance between a commitment to protect and improve the quality of life and economic stability of our nation and a mandate to focus limited pollution-control resources on those problems posing the greatest threat to the environment and to the economy. Striking such a balance also contributes to maintaining and improving our nation's competitiveness in international markets.

Main Findings and Conclusions

Environmental risk assessment is a powerful tool for solving environmental problems and allocating resources. Limitations currently associated with environmental risk assessment result from two factors: (1) fundamental lack

of knowledge in certain areas and (2) a concentration on the use of generalized hazard assessment techniques. Current methods for estimating environmental exposure and effects do not provide the necessary depth of understanding required for risk assessment and ignore the effects of multiple toxicants and the complex dynamics of ecosystem functions. Present understanding of ecosystem structure and function is also inadequate to determine when significant disruption is imminent and what constitutes unacceptable change.

Four key areas are recognized as needing substantial research to improve environmental risk assessment:

1. Risk assessment methodology;
2. Aquatic toxicology;
3. Terrestrial toxicology; and
4. Chemistry, fate, and modeling.

Risk Assessment Methodology

A significant amount of research is needed to validate and improve the risk assessment process itself. Large-scale validation studies using whole ecosystems are envisioned in which laboratory-to-field extrapolations can be verified for a range of chemicals with varying physical, chemical, and toxicological properties in different environments.

For the risk assessment process to work, specific effects endpoints need to be identified. Development of ecologically significant endpoints requires an increased research on the biology, physiology, and ecology of terrestrial and aquatic biota to better interpret the ecological significance of observed changes and predict higher-level effects (e.g., population) from simple toxicological data bases. Environmental exposures need to be better quantified and associated uncertainties identified. Currently there are no generally accepted or commonly used ecological effects models.

Communication of the risk assessment process needs to be improved. The challenge is to reduce complexity to an understandable, informative message for regulators, those regulated, professionals, elected officials, and the general public. The development of expert systems to enhance the data base management and computerized information-processing capabilities needed for risk assessment is also essential.

Aquatic Toxicology

In order to quantify and predict the biological effects resulting from exposure to contaminated sediments, the bioavailability of chemicals adsorbed to sediments and the factors controlling bioavailability must be quantified.

A better understanding of the microbial ecology of aquatic ecosystems is also needed, including an understanding of community interactions and of the regulation and metabolism of bacteria, photosynthetic bacteria, algae, protozoa, and fungi. In addition, increased use of genetically-altered organisms requires greater knowledge of their fate and transport with regard to population dynamics and ecology.

Research should be undertaken to improve aquatic risk assessment procedures by enhancing our knowledge of the biochemical, pharmacological, and toxicological mechanisms of xenobiotic chemicals and chemical mixtures in aquatic organisms. The ability to predict and confirm ecosystem stress from controlled laboratory and field investigations is essential to improving assessment procedures.

Quantitative structure-activity relationships and physiological/pharmacokinetic models need to be extended to allow extrapolation to untested chemicals. Furthermore, identification and measurement of ecosystem stress are hampered by the lack of a basic understanding of how toxicants affect the dynamics of aquatic systems encompassing interspecies interactions, nutrient cycling, decomposition, and energy flow.

Terrestrial Toxicology

A greater understanding of how chemical structure, soil properties, and other factors affect the biotransformation and biological availability of contaminants in the terrestrial environment is essential. Improved methods of measuring the routes of uptake and exposure to plants and animals of chemicals applied to terrestrial ecosystems will significantly improve terrestrial risk assessment methods.

The rational choice of appropriate sentinel species representative of a wide range of plants, animals, and microbes would enable exposure or toxicity to be recognized and would facilitate biological monitoring and assessment of remedial actions. The impact of microorganisms and vegetation on chemical concentrations in soils requires additional investigation to improve the ability to quantitatively estimate exposure concentrations.

At present there is a very limited data base for comparative biochemistry and physiology of most nonmammalian organisms of ecotoxicological concern. Extending this data base will assist in the inevitable need for cross-species extrapolation and will help identify surrogate and sentinel species.

Current field test methodology for evaluating the responses of animal, plant, and microbial populations to xenobiotics is inadequate. Furthermore, there is a need to find reliable alternatives to large-scale field testing.

Laboratory study designs are urgently needed to measure sublethal behavioral effects. Although these effects are difficult to observe in the field under natural conditions, they are important for the survival and productivity of species at all ecosystem levels.

In order to predict ecosystem effects from environmental residues, interactions between the biotic and abiotic components of the ecosystem must be better understood. In addition, ecosystem-level processes such as biogeochemical cycling, photoautotrophy, and resilience need to be more fully elaborated.

Chemistry, Fate, and Modeling

In order to improve the accuracy, speed, and utility of risk assessments, the problems of analysis of complex mixtures must be resolved. Because the behavior of toxic chemicals in the environment is determined in large part by their sorption-desorption mechanisms, knowledge of the kinetics of sorption and desorption is basic to understanding and predicting the effects of these chemicals.

There is a need to quantify the processes controlling the transport and fate of particulate matter (bottom, suspended, biotic, and abiotic) and its role in the transport and fate of toxic chemicals. Mechanisms of deposition and resuspension of particulate matter require additional research.

The major cycling mechanism of carbon in any ecosystem is biodegradation; thus, knowledge of biodegradation kinetics is crucial to the development of effective degradation models needed for risk assessment. Similarly, knowledge of atmospheric transport and fate processes is essential for evaluating human, animal, and plant exposures from chemical deposition. Such knowledge is also necessary for assessing the impact of natural and anthropogenic chemicals such as carbon dioxide and chloro/fluorocarbons on the atmosphere.

Basic techniques need to be developed to track genetic information through various environmental compartments in order to understand the fate and transport of genetically-altered organisms. Field validation of exposure models is also needed to provide evidence that model predictions in various compartments are credible. This research will improve the cost-effectiveness of laboratory testing and the utility of the data produced. Finally, probabilistic exposure models need to be more fully developed, because they form an integral part of risk assessment methodology.

Recommendations

- A new $75 million per year, 10-year research initiative is needed to ensure the progress required to develop effective environmental risk assessment strategies and methods.
- The new research initiative should build upon and enhance relevant existing research activities.
- Research fund allocations should be balanced among federal laboratories, universities, and other research organizations.
- The primary responsibility for this research lies with the United States Government. The initiative should include the Environmental Protection Agency, the Department of Agriculture, the Department of Health and Human Services, the Department of the Interior, the Department of Commerce, the Department of Defense, and the National Science Foundation.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

1.0 INTRODUCTION

1.1 BACKGROUND

The world faces many critical environmental issues that have an impact on the public welfare, the environment, and the economy. Improper disposal of hazardous wastes, pesticide impacts on terrestrial and aquatic life, forest decline, loss of habitat, consequences of genetically-altered organisms in the environment, contamination of groundwater and surface water, and a host of other issues demand that resources continue to be made available to solve these difficult environmental problems. To minimize the impact on our ecological resources, a research initiative to enhance our ability to develop environmental risk assessments is critically needed.

Environmental risk assessments estimate risks resulting from exposure of plants, animals, and ecosystems to pollutants and other stresses in air, water, and soil. The consensus of the scientific community is that environmental risk assessment is the most technically sound and cost-effective approach to providing the information needed to make decisions on the resolution of environmental problems. Environmental risk assessment provides a logical framework for comparing exposure with effects and provides an estimate of the probability that an effect will be observed. These attributes make the environmental risk assessment approach superior to other past and current approaches for assessing impacts on ecological resources.

Until ten years ago, impacts were assessed primarily in terms of effects only. Few mechanisms (except hazard assessment approaches) exist for linking exposure to effects and expressing the results in terms of probabilistic statements. Because an environmental risk assessment is able to articulate risk, the results of an environmental assessment are in a form that facilitates decision-making.

Critical environmental issues can best be addressed by the use of environmental risk assessment. If this approach is enhanced by the research identified in this document, it will be possible to establish priorities on the basis of comparative risks and then allocate limited resources to mitigate those problems that pose the greatest risk. The results of this effort will benefit our environment and our society.

Recognizing the value of applying the environmental risk assessment approach to environmental problem solving, the Society of Environmental Toxicology and Chemistry (SETAC) organized a workshop, "Consensus Research Needs and Priorities in Environmental Risk Assessment," to identify the research needed to enhance the development of environmental risk assessment methods. This report is a product of the workshop and can serve as the basis for an initiative to develop the resources needed to conduct the research identified.

This workshop is a continuation of a successful series of workshops called the Pellston Workshop Series. Since 1977, six workshops have been held, addressing a number of relevant environmental topics. These workshops have been organized and conducted by individuals who are SETAC members. Workshops held to date include:

- *Estimating the Hazard of Chemical Substances to Aquatic Life*—held in Pellston, Michigan, June 13-17, 1977, and published by The American Society for Testing and Materials as STP 657 in 1978.
- *Analyzing the Hazard Evaluation Process*—held in Waterville Valley, New Hampshire, August 14-18, 1978, and published by American Fisheries Society in 1979.
- *Biotransformation and Fate of Chemicals in the Aquatic Environment*—held in Pellston, Michigan, August 14-18, 1979, and published by American Society of Microbiology in 1980.
- *Modeling the Fate of Chemicals in the Aquatic Environment*—held in Pellston, Michigan, August 16-21, 1981, and published by Ann Arbor Science in 1982.
- *Environmental Hazard Assessment of Effluents*—held in Cody, Wyoming, August 23-27, 1982. Proceedings published by SETAC and Pergamon Press in 1985.
- *Role of Sediments in Regulating the Fate and Effects of Chemicals in the Aquatic Environment*—held in Florissant, Colorado, August 11-18, 1984. Proceedings to be published by SETAC and Pergamon Press in 1987.

1.2 SOCIETY OF ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY

The Society of Environmental Toxicology and Chemistry (SETAC) is a 1200-member professional society founded in 1979 to provide a forum for individuals and institutions engaged in the study of environmental problems, management and regulation of natural resources, education, research and development, and manufacturing and distribution. It is the only professional society that specifically brings together environmental scientists and engineers from academia, government, industry, and public-interest groups to provide research, education, and training in environmental risk assessment. SETAC provides a forum through meetings, publications, and workshops for communication among professionals involved in the use, protection, and management of our environment. The goals of SETAC are pursued through activities such as:

- Holding an annual scientific meeting comprising workshops and scientific paper presentations on topics related to environmental toxicology and chemistry.
- Publishing a monthly journal, *Environmental Toxicology and Chemistry*, a quarterly newsletter (SETAC News), and special publications (e.g., *Multispecies Toxicity Testing* and *Hazard Assessment of Effluents*).
- Organizing and sponsoring chapters nationwide to provide a forum for the presentation of scientific data and for interchange and study of information of more local concerns.
- Providing advice and counsel to technical and non-technical persons, groups, or institutions about scientific issues through a number of standing and ad hoc committees.

This workshop, "Consensus Research Needs and Priorities in Environmental Risk Assessment," was organized by SETAC's Technical and Governmental Affairs Committees to assess a critical need perceived by the membership to enhance capabilities through research for conducting environmental risk assessment. SETAC gratefully acknowledges the financial contributions of the workshop sponsors:

- U.S. Army Medical Research and Development Command
- U.S. Army Chemical Research Development and Engineering Center
- The Procter and Gamble Company
- The National Agricultural Chemicals Association
- Dow Chemical Company
- U.S. Environmental Protection Agency.

1.3 APPROACH TO DEVELOP CONSENSUS RESEARCH NEEDS AND PRIORITIES

To develop consensus research needs and priorities in environmental risk assessment, scientists representing a broad range of technical expertise were assembled for a one-week workshop. The workshop was held August 16-21, 1987 at the Village at Breckenridge, Colorado.

The workshop objectives were to identify specific research needs in environmental risk assessment, to enhance communication, and to provide a forum for transfer of information among researchers and decision-makers from government, industry, academia, and public-interest groups. Additional objectives were to identify research needed to solve current problems by means of proper environmental risk assessment, and to develop a strategy to enhance the use of environmental risk assessment in addressing environmental problems.

Workshop participants represented governmental organizations, universities, public-interest groups, industry, and contract research laboratories. Participants were chosen to provide the technical expertise needed to address research needs in environmental risk assessment. Technical expertise included aquatic and terrestrial toxicology, chemistry, environmental fate, transport, and modeling, and ecology.

During the initial phase of the workshop, keynote presentations were made by individuals representing SETAC, the U.S. Environmental Protection Agency's Office of Research and Development and Science Advisory

Board, the President's Office of Science and Technology Policy, trade associations, and universities. These speakers articulated key environmental risk assessment research directions from their organizations' perspectives, and illustrated approaches for best utilizing the results of the workshop to assist in the enhancement of the use of environmental risk assessment.

Prior to the workshop, each participant was asked to prepare a list of research needs to better improve our understanding and conduct of environmental risk assessments. Those preliminary research needs were then used as the basis for developing the consensus research needs and priorities. Participants were placed into one of six workgroups: Terrestrial Toxicology, Aquatic Toxicology, Chemistry/Fate/Modeling, Risk Assessment Methodology, Implementation, and Synthesis (Table 1.1). Each workgroup was responsible for the development and integration of research needs and priorities within its technical area in order to identify the technical research needed to best improve our understanding and use of environmental risk assessment. The Implementation workgroup had the task of preparing a plan on how to best enhance the use of environmental risk assessment in solving environmental problems, while the Synthesis workgroup was responsible for synthesizing the findings of the other workgroups into a united whole.

The outcome of the workshop is presented in this report. Section 2 provides a perspective on environmental risk assessment and discusses the benefits to society of applying environmental risk assessment to environmental problems. The adequacy of environmental risk assessment methods and research needs to improve those methods is described in Section 3. The application of environmental risk assessments to environmental problems is illustrated in Section 4. Research needs in environmental risk assessment, exposure analysis, and effects are identified in Section 5. Appendices A through D provide detailed explanations of those research needs presented in Section 5, including summaries of the issues involved, justifications for further research, and plans for that proposed research. Appendix E is a glossary of technical terms used in this report, and Appendix F is a roster of participants in the workshop.

TABLE 1.1 ENVIRONMENTAL RISK ASSESSMENT RESEARCH NEEDS WORKGROUPS

TERRESTRIAL TOXICOLOGY

Dr. Ronald Kendall* —Director, Institute of Wildlife Toxicology, Western Washington State University
Dr. Barbara Walton—Environmental Toxicologist, Oak Ridge National Laboratory
Dr. Bill Williams—Team Leader, Wildlife Toxicology, U.S. Environmental Protection Agency
Dr. Richard DiGiulio—Assistant Professor of Ecotoxicology, Duke University
Dr. James Gagne—Senior Product Development Manager, American Cyanamid Company
Dr. Molly R. Whitworth—Section Leader, Contaminant Ecology Research, U.S. Fish and Wildlife Service
Dr. Peter Greig-Smith—Head of Environmental Research Group, Ministry of Agriculture, Fisheries, and Food, United Kingdom
Dr. James Gillett—Director, Institute for Comparative and Environmental Toxicology, Cornell University

AQUATIC TOXICOLOGY

Dr. Wayne Landis* —Research Biologist, U.S. Army Chemical Research Development and Engineering Center
Dr. Thomas Sabourin—Environmental Toxicologist, Battelle, Columbus Division
Dr. Paul Mehrle—Chief Biologist, National Fisheries Contaminant Research Center, U.S. Fish and Wildlife Service
Mr. Steven Schimmel—Research Aquatic Biologist, U.S. Environmental Protection Agency
Dr. William Van der Schalie—U.S. Army Medical Research and Development Command

Continued

TABLE 1-1 ENVIRONMENTAL RISK ASSESSMENT RESEARCH NEEDS WORKGROUPS (CONTINUED)

CHEMISTRY/FATE/MODELING

Dr. Robert Huggett*—Head of the Division of Chemistry and Toxicology. Virginia Institute of Marine Science
Mr. Robert B. Ambrose—Environmental Engineer, U.S. Environmental Protection Agency
Dr. John P. Connolly—Associate Professor, Manhattan College
Dr. Ralph Portier—Assistant Professor, Louisiana State University
Dr. Robert Rapaport—Environmental Engineer, The Procter and Gamble Company
Dr. Armon Yanders—Director, Environmental Trace Substances Research Center, University of Missouri
Dr. William Wood—Team Leader, U.S. Environmental Protection Agency, Pesticide and Toxics

RISK ASSESSMENT METHODOLOGY

Dr. Richard Kimerle* —Senior Research Fellow, Monsanto Company
Dr. Robert Graney—Manager, Environmental Toxicology, Hoechst-Roussel
Dr. Glenn Suter—Research Staff Member, Oak Ridge National Laboratory
Dr. Peter Van Voris—Program Manager, Battelle Pacific Northwest Laboratories
Dr. Christopher Lee—Section Manager, Ecotoxicology Section, Unilever Research
Mr. Rodney Parrish—Research Aquatic Biologist, U.S. Environmental Protection Agency
Dr. Margaret Rostker—Special Assistant, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency

IMPLEMENTATION

Dr. William Bishop*—SETAC Vice President, Associate Director, Environmental Safety Department, Procter and Gamble
Dr. Alvin Young—Senior Policy Analyst for Life Sciences, President's Office of Science and Technology Policy
Mr. Donald Ehreth—Deputy Assistant Administrator, Office of Research and Development, U.S. Environmental Protection Agency
Dr. John McCarthy—Director of Scientific Affairs, National Agriculture Chemicals Association
Dr. Gerald Poje—Environmental Toxicologist, Pollution and Toxic Substances Control Division, National Wildlife Federation
Dr. Terry Yosie—Director, Science Advisory Board, U.S. Environmental Protection Agency
Mr. Randy Scott—Acting Director, Office of Environmental Audit, U.S. Department of Energy

SYNTHESIS

Dr. Kenneth L. Dickson* —SETAC President; Director, Institute of Applied Science, North Texas State University
Dr. James A. Fava—SETAC Technical Committee Chair; Manager, Environmental Technology and Assessment, Battelle Columbus Division
Dr. William Adams— SETAC Government Affairs Committee Chair; Associate Fellow, Monsanto Company
Dr. Robert Larson—Section Head, Environmental Microbiology, Procter and Gamble
Dr. Gary Dickson—Acting Director, Research and Development Planning, Agricultural Division, CIBA-GEIGY

*Workgroup Chair

2.0 A PERSPECTIVE ON ENVIRONMENTAL RISK ASSESSMENT

Before 1977, potentially adverse environmental impacts were typically evaluated by considering effects only. Arbitrary toxicity limits were used to estimate the safety of chemicals. During the past ten years, the concept of coupling exposure with effects, a process called "hazard assessment," has been used to conduct environmental assessments.

The hazard assessment process calculates a quotient or margin of safety by comparing the toxicological endpoint of interest (usually an estimate of the safe concentration) to an estimate of the exposure concentration. A judgment is then made on the adequacy of the margin of safety. Toxicological and exposure data are collected in tiers, allowing for decisions to be made with minimum data, provided that the margin of safety is large enough. Large uncertainty factors have to be included in the margins of safety for minimum data bases, while smaller uncertainty factors can be used with larger data bases. The uncertainty factors that are applied to safety decisions come from a general understanding contained in published literature on the variability that exists in species responses, life stages, short- and long-term endpoints, and test methods.

The hazard assessment approach has been used over the past decade by industry and regulatory agencies in evaluating the safety of new and existing chemicals under the Toxic Substances Control Act (TSCA), pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), effluents under the Clean Water Act (CWA), and the cleanup of hazardous waste sites under the Comprehensive Environmental Response Compensation and Liability Act/Superfund Amendments and Reauthorization Act (CERCLA/SARA).

Risk assessment is the process of assigning magnitudes and probabilities to adverse effects resulting from human activities or natural catastrophes. In the last few years, risk assessment has been recognized as a valuable tool to support decisions about actions that may have undesirable effects. Risk assessment consists of formal scientific techniques that (1) integrate knowledge about a contemplated action and its possible effects, (2) account for uncertainty associated with that knowledge, and (3) express results probabilistically in order to account for both knowledge and uncertainty. Risk assessment provides a sound technical basis for making rational management decisions. Risk management is the process of making decisions about the acceptability of risks and the need for risk reduction.

Risk assessment was originally developed as a part of the actuarial techniques of the insurance industry to estimate probabilities of events that result in claims. It has been extended by engineers to estimate the probabilities of catastrophic failures of engineered systems such as aircraft and nuclear power plants. More recently, it has become an important tool in the health industry for estimating probabilities of diseases among people exposed to a range of toxic chemicals and mixtures such as cigarette smoke or emissions from coke ovens.

Environmental risk assessments estimate risks that may result from events in the environment. Most often they deal with pollution of the air, water, and soil. They may also be concerned with physical modifications of the environment and with natural catastrophes. The branch of environmental risk assessment that deals specifically with effects on plants, animals, and ecosystem properties is termed ecological risk assessment.

Environmental risk assessment differs from previous approaches to estimating environmental effects, such as hazard assessment, in that risk assessment employs scientific methods to estimate probabilities of clearly prescribed effects. Hazard assessments have relied more on margin of safety and the expert judgment of the assessor than on formal techniques such as mathematical and statistical models that define the magnitude of uncertainty in the effects and exposure estimates. While uncertainty has been recognized to exist, it has not been acknowledged that uncertainty results in some probability that effects and/or exposure will be more or less severe than expected. Advances made in assessment modeling, environmental chemistry, and environmental toxicology have begun to make it possible to use formal risk assessment methodologies.

An example of an environmental risk assessment is the National Crop Loss Assessment Network (NCLAN), which addressed the effects of ozone and sulfur dioxide on crop production. NCLAN had a clear endpoint — the reduced production of four major crops expressed in dollars. NCLAN developed a closely integrated program of experimentation and modeling and expressed the uncertainty of its results as probability-density functions on production losses for each alternate air quality criterion. Thus NCLAN provided the EPA with a clear expression of the consequences of alternative decisions. NCLAN and the few other examples of good environmental risk assessment have addressed major national problems at considerable expense. New methods must now be developed to make the benefits of risk assessment available to routine assessments such as registration of pesticides and toxic substances, prioritization of hazardous waste sites, natural resource damage assessments, and dredge-and-fill permits. To do so requires focused research applicable to environmental risk assessment methods.

Environmental risk assessment can provide the following benefits to the risk manager, the business and scientific communities, and the public:

1. *Environmental risk assessment will provide a firm scientific basis for decisions. This will improve public welfare and stewardship of the environment.*
2. *Improved understanding of risk and risk perception will result in improved communication of risk to the public.*
3. *Risk-based environmental decisions will provide a means of comparing risks so that resources can be efficiently allocated among environmental issues and rational policies can be formulated.*
4. *Environmental risk assessment will provide a means of incorporating uncertainty in the assessment process. The use of uncertainty measurements improves confidence in the decision-making process by evaluating the potential consequences of a decision based on incomplete knowledge. This is done by comparing the relative magnitudes of uncertainties about each step in the causal chain between the initial event (e.g., release of a toxic chemical) and ultimate consequences (e.g., destruction of a bird population).*
5. *Formal risk assessment will provide consistent results. It uses scientifically reviewed methodologies that are available to regulated entities and the public, thus increasing confidence in the decision process.*
6. *Allocation of resources for investigation and research on a particular environmental issue will be made effectively. This is done by addressing the sources of greatest uncertainty identified in the risk assessment process.*
7. *The ability to conduct consistent and comprehensive risk assessments will reduce the uncertainty associated with bringing new chemicals and technologies to market. It will increase the confidence of all sectors of the community in the safety of the environment, thus increasing support for innovation. This will increase the competitiveness of the business community by allowing it to take the lead in the introduction of new materials and processes.*

3.0 RESEARCH NEEDS IN ENVIRONMENTAL RISK ASSESSMENT

As a result of activities that have improved modern society's standard of living and the concurrent reliance upon the use of chemicals, we are faced with the dilemma of assessing potential risks to man and the environment. At the present time, we are limited in our ability to conduct scientifically defensible risk assessments for these chemicals. These limitations can best be addressed by a national research initiative.

3.1 LEGISLATIVE MANDATES

The goal of protecting and conserving our nation's living resources (forests, wetlands, fisheries, etc.) has a long history. Achievement of this goal has been codified in several pieces of legislation over the past two decades. Examples of such legislation include:

- National Environmental Policy Act
- Clean Water Act
- Federal Insecticide, Fungicide and Rodenticide Act
- Toxic Substances Control Act
- Comprehensive Environmental Response, Compensation and Liability Act
- Wetlands Protection Act
- Endangered Species Act
- Fish and Wildlife Coordination Act
- Federal Land Policy Management Act
- Migratory Bird Treaty Act
- National Fisheries Protection Act.

These laws address issues related to the assessment of impacts from existing and new technologies, protection of species diversity, conservation of natural resources, and assessment of the risks posed by the production, use, and disposal of pesticides and industrial chemicals. Implementation of this legislation at the federal, state, and local level can benefit from the application of a consistent, systematic framework for conducting environmental risk assessment. However, our present capacity to estimate ecological and environmental risks is not sufficient to ensure the prevention of other costly, and possibly irreversible damage to essential biogeochemical cycles or potential extinction of endangered species and ecosystems. *For these reasons, data gaps and methodological shortcomings in environmental risk assessment need to be addressed by a national research initiative.*

3.2 CURRENT LIMITATIONS IN ENVIRONMENTAL RISK ASSESSMENT

Current test methodology and specific endpoints have been designed to support the relatively simplistic, but nonetheless valid process of hazard assessment. Although many of the methods are scientifically sound and have been successfully used to support the needs of existing legislation, they have a number of limitations, sometimes severe, in relation to their utility in risk assessment. There are also gaps in available methodologies that must be filled in order to accomplish effective and comprehensive risk assessments.

At present, potential environmental impacts of chemicals are analyzed primarily through hazard assessments, which do not explicitly define ecological endpoints such as forest production or protection of endangered species, but only compare exposure and specific effect test endpoints. By only comparing exposure and test endpoints, hazard assessments ignore the complex dynamics of (1) contaminant concentration in each of the media to which the organism is exposed, (2) the duration of exposure, (3) the severity of effects, (4) the proportion of organisms that are affected, and (5) ecosystem-level considerations such as resistance and resilience.

Current exposure and effects methodologies do not provide the depth of understanding of the chemical and biological mechanisms that environmental risk assessment requires. Analytical chemical methods are inadequate to

provide a picture of chemical composition and speciation through time and are limited in their ability to identify the transfer coefficients essential to the modeling processes necessary for risk assessment.

In relation to the effects of chemicals, commonly used methods do not adequately address the effects of intermittent exposure, incremental dose, indirect effects, and the toxicity of intermediates and complex mixtures. Validated methods for determining effects at the population, community, and ecosystem level are also limited. The ability of current approaches to extrapolate results of laboratory tests into field situations is unknown and may lead to overconservatism in many cases. Our understanding of ecosystem structure and function is inadequate to determine when significant disruption is imminent and what constitutes unacceptable change. Similarly, while it is recognized that various compartments of the terrestrial and aquatic ecosystems may be resilient to xenobiotic impacts, these mechanisms are not understood. Few means exist to express dynamic ecosystem processes such as production, respiration, nutrient cycling, and energy flows in a form suitable for risk assessment.

Improved risk assessment methods will increase the efficiency and cost-effectiveness of environmental risk assessments, thus increasing the assessor's confidence in his or her conclusions and allowing better decisions to be made.

3.3 IDENTIFIED RESEARCH NEEDS IN RISK ASSESSMENT

Specific research needs that will address many of the limitations already discussed have been identified in this report. Correction of these deficiencies can only be accomplished through research projects designed to answer specific questions. Such research programs must address all components of risk assessment (Figure 3.1), and must contain a coordinated framework that emphasizes communication among the disciplines. More effective communication will ensure that toxicity test results, analytical chemistry measurements, and other measures are generated in a manner compatible with the risk assessment process.

As a starting point, funding in the area of risk assessment procedures should begin with a thorough examination of existing procedures and a review of the supporting literature. Reviewing past and current methodologies will provide insights into and understanding of the approaches that have been used and that appear to be most useful in assessing environmental risks. Directions for future efforts can be identified and refined by review of the past and present.

For the risk assessment process to work, specific effects endpoints need to be identified. Development of ecologically significant endpoints requires an increase in research on the biology, physiology, and ecology of terrestrial and aquatic biota. Greater understanding in these areas will enhance the ability of the risk assessor to interpret the ecological significance of observed changes and predict higher-level effects (e.g., population) from simple toxicological data bases. Environmental exposures need to be better quantified and the associated uncertainties identified. This can be accomplished by:

1. developing toxicity test procedures that more accurately reflect environmental exposure;
2. investigating the influence of behavior on chemical exposure;
3. better defining what to monitor and how to monitor in the environment;
4. developing approaches to determine whether a change is environmentally significant;
5. identifying techniques to extrapolate among geographical regions by using data from similar ecosystems; and
6. developing models that provide estimates of exposure. Such models are only useful if they can be parameterized with data available to the risk assessor and if they accept and integrate uncertainty estimates. Therefore, any environmental exposure research in the aquatic or terrestrial environments must consider these factors.

Models useful for predicting ecological effects are also needed. Currently, there are no generally accepted or commonly used ecological effects models. Development of these models also requires basic research on the biol-

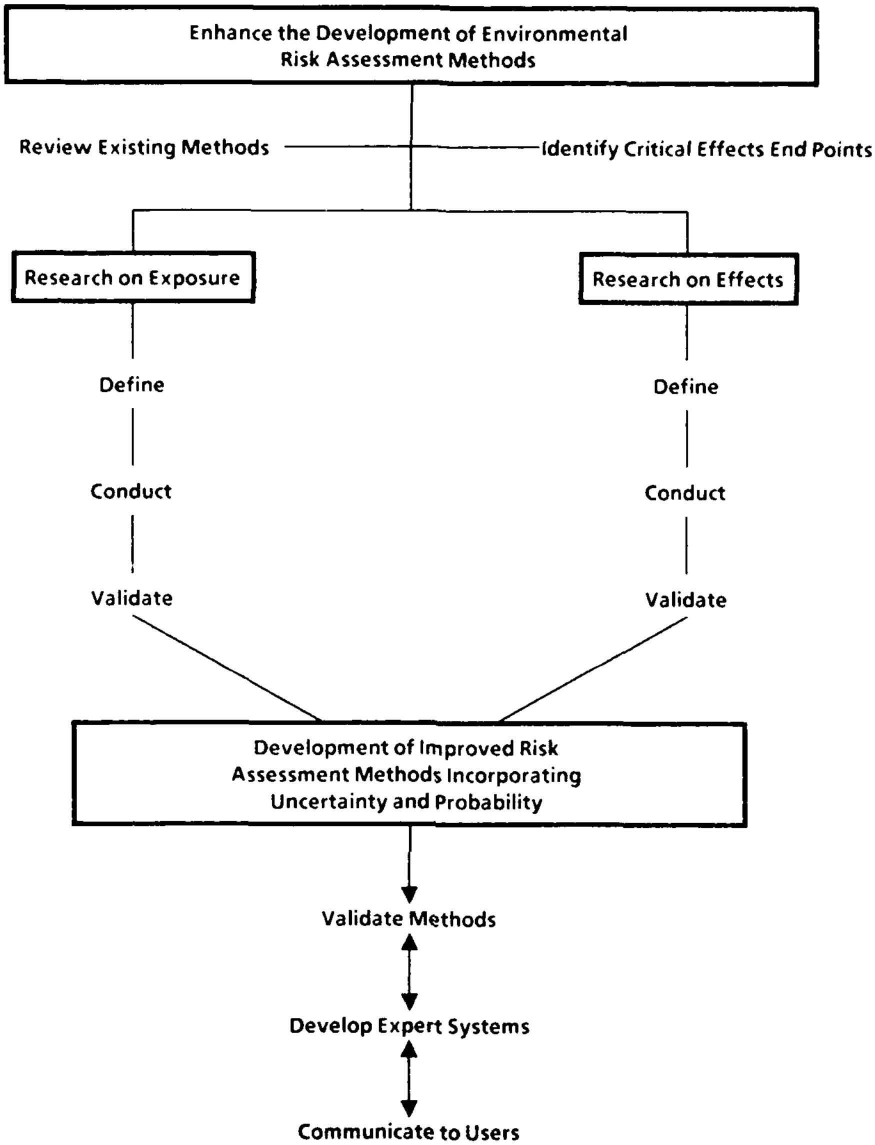

FIGURE 3.1 DEVELOPMENT OF ENVIRONMENTAL RISK ASSESSMENT METHODS

ogy and ecology of aquatic and terrestrial biota. For effects models to be useful, clearly defined endpoints must be established so that the models can be constructed appropriately.

The hazard assessment process now employed in most situations does not adequately include the uncertainty of the data estimates or of the model results. The environmental fate and effects research proposed during this workshop must include consideration of the variability and uncertainty inherent in measurements. Test procedures and models that include the concept of uncertainty need to be developed and refined, so that uncertainty can be incorporated into risk assessments and subsequently conveyed in a useful way to those who make or review decisions.

The need exists to make the best scientific expertise available for the risk assessment decision-making process. The use of expert systems in the risk assessment process can assist in achieving this goal. Once in place, expert systems will be used as a source of information in decisions dealing with the safety of chemicals in the environment.

Communication of the risks associated with the use and disposal of chemicals needs to be improved. The challenge is to reduce a very complex process to a simple, understandable, yet informative message that explains to regulators, those regulated, involved professionals, elected officials, and the general public how they are affected by the process. Research concerning the best and most appropriate mechanism to provide this information is needed.

The all-encompassing research need facing environmental risk assessment is validation of the process itself. Many of the needs discussed above can be investigated in large-scale validation studies. Critical needs such as endpoints, laboratory-to-field extrapolations, and understanding of the ecological significance of changes should be addressed. The output of such studies would provide risk assessors with the relationship between the amount of chemical and toxicological data collected and the resulting uncertainty in the risk assessment decision. Validation efforts should be undertaken in different types of environments and for chemicals of varying physical, chemical, and toxicological characteristics.

Section 5 and Appendices A, B, C, and D of this report contain specific research needs to advance the state of the art of environmental risk assessment. The proposed research initiative should address these needs.

4.0 APPLICATION OF ENVIRONMENTAL RISK ASSESSMENT TO ENVIRONMENTAL PROBLEMS

A multitude of existing and emerging environmental issues confront the nation and the world. Each specific issue can have impacts at local, regional, and even global levels, and can involve air, water, sediment, soil, and groundwater with multimedia interactions. Although the technology exists to solve each of these issues, the costs associated with many of the solutions are so large that cost effective means of resource allocation must be found if timely and substantive efforts are going to be effected for all issues.

At present, all decision-makers associated with policy or risk management roles are limited in their ability to answer the following sequence of questions:

1. *Is there currently an ecological problem?*
2. *If so, what is the extent and magnitude of the problem?*
3. *What are the current trends and or the anticipated future trends that define the potential problem?*
4. *What are the most probable causes of the problem?*
5. *What changes in policy or control mechanisms can be expected to reduce the current or potential risk?*
6. *What is the most cost-effective remedial action?*
7. *How do we measure the effectiveness of any remedial action?*

Environmental risk assessment can help answer the above questions and contribute to the development of cost-effective assessment and remedial strategies in several ways. First, by evaluating the existing scientific data bases, environmental risk assessment can quantify the magnitude and seriousness of identified environmental problems. Conversely, it can show that a low probability of effects exists. Where consequence predictions are surrounded by uncertainty, environmental risk assessments will recognize and quantify that uncertainty, thereby providing an essential element for decision-makers. Recently, for instance, qualitative and quantitative evaluations of the human and environmental risks from stratospheric ozone depletion have led to a re-examination of the research and regulatory priorities of this problem.

Second, the process of assessing today's risks reveals data gaps or uncertainties that signify the need for additional research. For example, accidental spills may have environmental impacts significantly different from those produced by chronic pollutant discharges. The need to understand how spills affect the long-term resiliency and recovery capabilities of ecosystems thus emerges as a research priority.

Third, the application of environmental risk assessment provides a quantitative measure of the reduction of environmental risk resulting from various remedial strategies. Thus, it provides a cost-effective basis for allocating resources.

The application of environmental risk assessment methods for evaluating and solving environmental problems is becoming widely used and is recognized as a scientifically sound approach, but this approach is currently limited by a lack of critical information in key areas. Additional research is needed to enhance the state of the art of environmental risk assessment procedures.

To demonstrate the need for additional research, examples are presented below to show how the environmental risk assessment approach could be applied to several of the following key national issues:

- Methods of proper waste disposal
  —industrial waste
  —municipal waste
  —waste site remediation

- Protection of natural waters
  - —surface water (streams, wetlands)
  - —groundwater
  - —coastal waters
- Impacts of genetically-altered organisms in the environment
- Safe and effective use of agricultural chemicals
- Control methodologies for non-point source contaminants
- Atmospheric process changes affecting biota
  - —acid precipitation
  - —ozone depletion
  - —global warming—chemical contaminants
- Influence of sediments on water quality and biota
- Effects of complex chemical mixtures on biological systems
  - —effluents
  - —irrigation drainage waters
  - —dredged materials
- Potential environmental effects of newly developed industrial chemicals
- Maintenance of natural resources and habitat quality
- Communication of risk information to various audiences, including scientists, regulators, policymakers, and the general public.

The following examples specify how environmental research assessment methods could be brought to bear on environmental problems related to waste disposal, biotechnology, agricultural chemicals, atmospheric contamination, complex mixtures, natural resource contamination, and groundwater quality.

4.1 WASTE DISPOSAL: ENVIRONMENTAL RISK ASSESSMENT

There is a clear need to extend the implementation of environmental risk assessment techniques into the overall strategies for disposal of industrial and municipal wastes and to improve the risk assessment methodologies being used. Application of environmental risk assessment procedures to waste disposal is a scientifically sound and cost-effective basis for making decisions on disposal and site cleanup methodologies as well as for providing a measure of the potential for environmental impact from past, present, or future disposal methods.

Wastes are currently disposed of in all environmental media by such routes as incineration, release of effluents, and deposition in landfills and septic systems. Tracking potentially toxic chemicals is a complex task, and the assessment of the risk associated with waste disposal will certainly benefit from improved understanding of the physical, chemical, and biological processes involved. Chemical transport from wastes through processes such as air emissions, land runoff, soil leaching, and sedimentation leads to the presence of potentially toxic chemicals in terrestrial and aquatic environments (Figure 4.1).

Research is proposed on exposure and effects to enhance the scientific community's ability to better use environmental risk assessment procedures in both forecasting and handling current problems associated with the fate, transport, and effects of toxic chemicals at waste sites. The benefit of such research will be the ability to make cost-effective scientific decisions about waste disposal alternatives. On the basis of quantitative risk measurement, prioritization of waste sites for remediation can be accomplished effectively. The potential exists to significantly reduce the nation's risk associated with disposal methods and waste site chemical contaminants.

The major inputs to environmental risk assessment models for waste disposal are the sources, exposures, and effects shown in Figure 4.2. Improved understanding and modeling of the relationships between the components

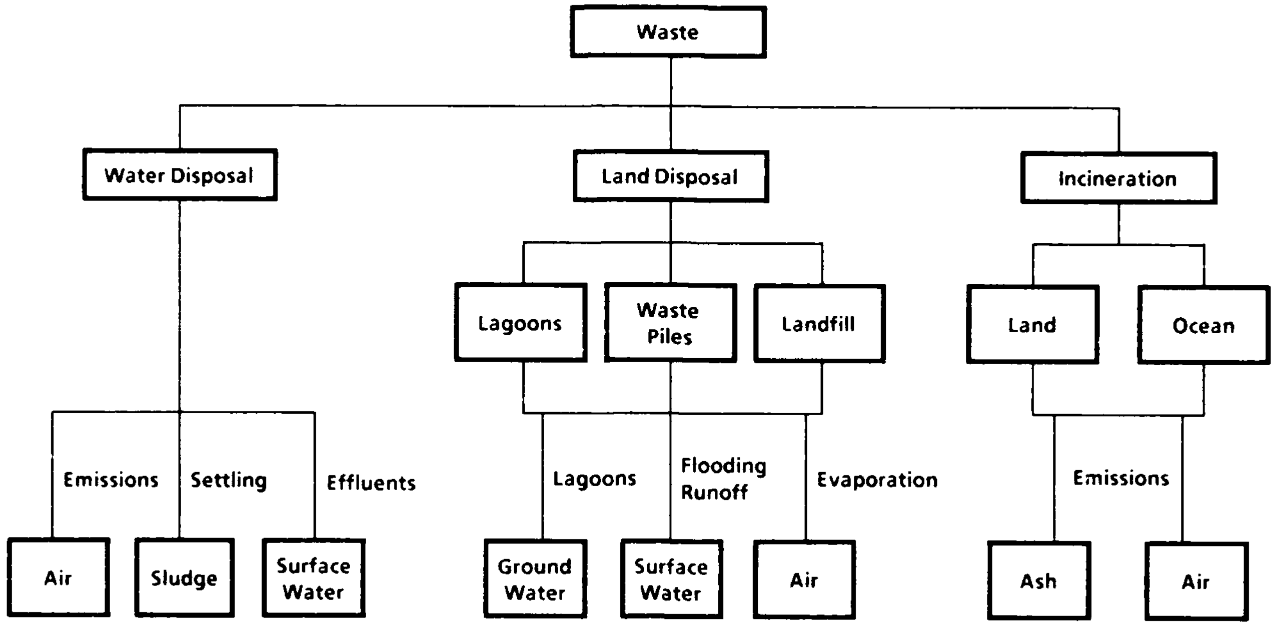

FIGURE 4.1 SUMMARY OF ENVIRONMENTAL FATE AND TRANSPORT PROCESSES OF DISPOSED WASTE

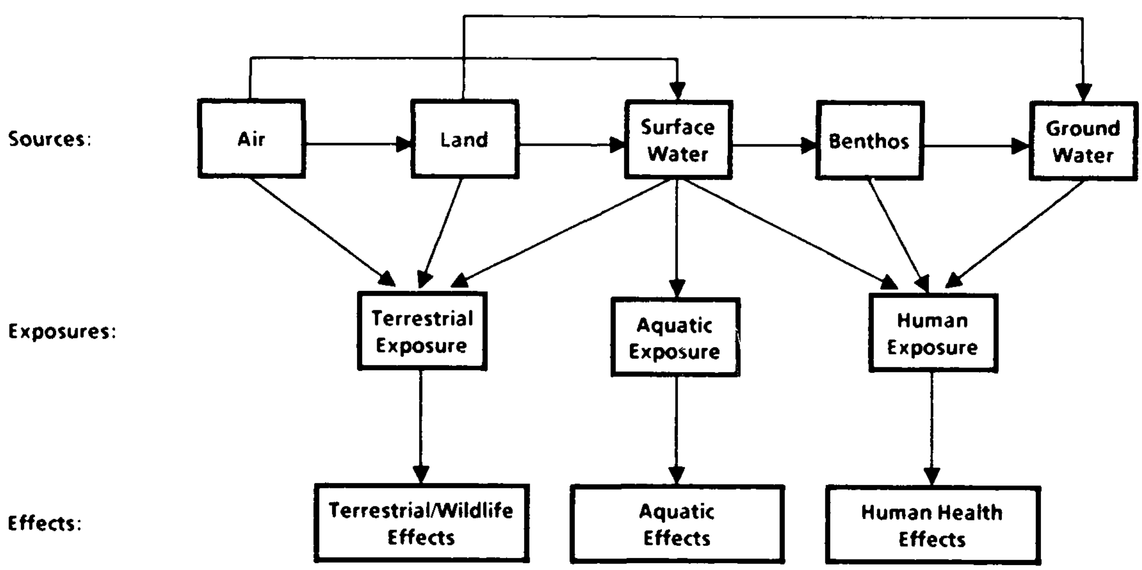

FIGURE 4.2 RELATIONSHIPS AMONG SOURCE, EXPOSURE, AND EFFECTS OF TOXIC CHEMICALS DERIVED FROM DISPOSED WASTE

shown in Figure 4.2 will be necessary to perform the appropriate risk assessments. To illustrate this need, two brief examples follow.

Example 1:

The movement of chemicals from one medium to another by sorption-desorption is a key factor in the issue of waste disposal and cleanup. Simply knowing that a toxic chemical is present in a given environmental compartment

is not enough. In order to know whether or not it will have an undesirable effect, we need to know how much of the chemical is available to living organisms in a form that can produce an effect. Modern analytical techniques can tell us that a chemical is present, even when it is present in ultratrace amounts, but these techniques do not usually tell us the extent of the biological availability or how the materials behave in association with various soils, sediments, or solvents. *Knowledge of the sorption-desorption behavior is critical for predicting rates of movement in aquatic, terrestrial and atmospheric media, and for assessing what this movement is likely to mean to the ecosystem.*

Example 2:

Contamination of groundwater aquifers that serve as drinking water sources can result from toxicants leaching from waste sites. Present methods are limited in their ability to quantify the risks posed by these activities because of the heterogeneous nature of the underlying strata and the channeling effects that can occur as a result of fractured media. At the present time, the effects of channeling result in non-quantitative measures of chemical movement through fractured strata. Present uncertainties in chemical transport contribute to unreliable estimates of exposure to target organisms via movement in the groundwater. *The proposed research is designed to improve estimates of chemical movement in fractured media and thereby enhance the overall risk assessment process.*

4.2 BIOTECHNOLOGY: ENVIRONMENTAL RISK ASSESSMENT

Biotechnology is an emerging science that deals with the intentional change of the genetic configuration of an organism (i.e., plant, animal, or microorganism). The objectives of these genetic changes are either (1) to produce a chemical, pesticide, or drug for use in commerce, or (2) to produce an organism that will have a beneficial effect when released to the environment. An example of the first objective is the production of human insulin by introduction of the appropriate gene sequences into a bacterium. In the latter objective, the organism might be a bacterium that is purposely sprayed on an agricultural field to act either directly as a microbial pest control agent or indirectly to produce a chemical that has a pesticidal effect.

Genetically-altered organisms are not limited to bacteria. An enormous research effort is currently underway to introduce herbicide-resistant plants that have been produced by splicing bacterial genes into their genome. In either objective, considerable concern has arisen over the potential environmental risks of either deliberate or accidental release of genetically-altered organisms into the environment.

The process of biotechnology environmental risk assessment is one that provides a quantitative estimate of the risk to the environment associated with the production of genetically-altered organisms. The application of risk assessment procedures to the biotechnology area is an emerging science that requires extensive investigation and research effort to develop and apply appropriate methodologies.

Biotechnology is a growing industry of great promise on an international scale. The benefits of applying accurate environmental risk assessments to this industry include protection of the environment and enhancement of the competitiveness of the U.S.-based biotechnology industry. The benefits of biotechnology include increased efficiency of agricultural production through development of disease-resistant plants, waste cleanup by means of genetically-designed microbes, production of pharmaceuticals and diagnostics, and the general resultant economic prosperity. Such benefits will not be achieved if we do not learn how to manage the risks associated with biotechnology in a cost-effective manner.

The research that is proposed in the biotechnology area is designed to enhance environmental risk assessment procedures for biotechnology by providing answers to critical elements of the risk assessment process. Examples of the types of questions that need to be answered are shown below. (Additional research needs are described in Section 5.)

1. What are the ecological effects of the introduced organism on the species composition, community structure, and metabolism (i.e., biogeochemical cycles) of an ecosystem?
2. What is the probability of survival, and what are the rates of reproduction and migration of a genetically-altered organism?
3. What is the significance and frequency of gene transfer from the genetically-altered organisms to naturally occurring organisms?
4. What are the parameters controlling the expression of the introduced genetic element in the environment?
5. What are the effects of ecological factors on the genetic stability of the altered organism?
6. What are the effects of the genetic background of the natural populations on the continued existence of the introduced genetically-altered organism and the inserted gene sequence?
7. Are there management strategies that lower the risks associated with a genetically-altered organism (i.e., suicide gene, containment organism sterility)?
8. What possible environmental risks can be attributed to the effluents, both chemical and biological, of biotechnological processes?

Research efforts to answer these and related questions will mean a significant enhancement of our understanding of and confidence in the rapidly expanding discipline of biotechnology and our ability to perform environmental risk assessments related to this new area.

4.3 AGRICULTURAL CHEMICALS: ENVIRONMENTAL RISK ASSESSMENT

Agricultural or plant protection chemicals are currently an essential component of agricultural production systems throughout the world and will remain so in the future. In short, these chemicals are unique in that they are intentionally released into the environment because of their benefits, even though by their nature, plant protection chemicals are toxicants that may affect non-target organisms. The use of environmental risk assessment methods for determining the environmental risk associated with intentional release of agricultural chemicals is an ideal approach for protecting the environment and enhancing the decision-making process. The large amount of data required for registration of agricultural chemicals lends itself to the application of risk assessment methods. To further enhance the risk assessment process for application to agricultural chemicals, additional basic research is required to understand key environmental processes.

The proposed research will reduce uncertainties associated with evaluating the safety of agricultural chemicals. This will be accomplished through better ways of quantifying risks, more efficient use of existing data and computer models, and improved measures of chemical exposure and biological effects. The net effect will be better management of environmental exposure and a reduction in the risk of ecological effects.

Under the Federal Insecticide, Fungicide and Rodenticide Act, EPA is faced with the difficult task of determining the potential adverse effects of agricultural chemicals. The procedure now used by EPA for estimating the potential adverse effects of agricultural chemicals involves comparing the concentration of the chemical that causes a toxic effect in laboratory and field tests with the concentration that is expected to occur in the environment. This environmental hazard assessment approach is termed the quotient or ratio method. For low-to-moderately toxic compounds, the estimated concentration in the environment is often much lower than the concentration that causes toxic effects. As a result, the decision that adverse effects are unlikely to occur can be made with a high degree of confidence. However, as the estimated concentration of an agricultural chemical gets close to the concentration that causes effects in laboratory and field tests, the decision that adverse effects would not occur in the environment becomes more and more difficult to make. The consequence of this latter situation is that agencies such as EPA must make a decision that could:

1. incorrectly determine that an agricultural chemical is safe, thereby sanctioning the use of a harmful chemical; or

2. incorrectly determine that an agricultural chemical is unsafe, thereby prohibiting the use of a compound that provides economic benefit to both the farmer and the consumer.

It is in everyone's best interest to minimize decisions such as those described above and to maximize the number of times we can correctly determine that an agricultural chemical is safe or unsafe within defined probabilities. This can effectively be accomplished through use of environmental risk assessment methods.

4.4 ATMOSPHERIC CONTAMINATION: ENVIRONMENTAL RISK ASSESSMENT

Environmental risk assessment methods are readily applicable to solving atmospheric contamination problems. The principle of comparing exposure concentrations with effect concentrations, combined with quantitative risk measurements, is a scientifically sound approach for assessing the impact of atmospheric contaminants. To accomplish this in a more effective manner, additional information is needed to enhance the state of the art for environmental risk assessment methods.

The benefit of applying environmental risk assessment to the problem of atmospheric contamination is that risk assessment provides a means for cost-effective resource allocation. Environmental risk assessment provides a formal, quantitative, and robust methodology for determining key atmospheric contaminants and measuring the risk of each contaminant to the environment. This approach can efficiently identify the particular chemicals responsible for environmental impacts as well as identify environmental compartments (regions, populations) at greatest risk to damage. Furthermore, environmental risk assessment can provide a quantitative analysis—including determination of uncertainty—of the expected outcomes of given scenarios of pollutant control. These results could then become a critical component of cost-benefit analyses of various emission control strategies.

Important issues in the area of air quality include global warming associated with increased carbon dioxide concentrations derived from fossil fuel combustion, stratospheric ozone depletion associated with fluorohydrocarbon emissions, catastrophic releases of toxic chemicals, long-range transport and deposition of synthetic organic compounds such as pesticides and PCBs, and the impacts of air pollution on aquatic and terrestrial ecosystems, including acid precipitation.

Some problems of atmospheric contamination, such as fugitive emissions from landfills, waste incinerators, and factories, occur on the local scale, and risk assessment provides an efficient approach for their analysis and solution. However, many critical problems are manifest on large scales—regional, national, and global. This added complexity of scale further compels use of formal risk assessment techniques.

Deposition of atmospheric pollutants and resulting impacts on terrestrial systems, particularly forests, exemplify the need for adequate large-scale atmospheric environmental risk assessment. Forest decline, apparently caused by air pollution, is severe in central Europe and is rapidly advancing in parts of western Europe. The precise causes of this decline are unclear, but they appear to be largely associated with emissions of nitrogen and sulfur oxides from fossil fuel combustion and agricultural fertilizers and the concomitant photochemical production of other oxidants, such as ozone and hydrogen peroxide. Forest decline is currently far less severe in the United States, being limited to certain high elevation sites in the Appalachian Mountains. However, it is crucial that the issue be addressed now in the United States before forest decline becomes widespread. At the present time, risk assessment methods are restricted by a lack of information on methods of chemical analysis, dispersion modeling, appropriate indicators of ecological effects, and source identification. Additional research is needed.

The application of environmental risk assessment to the problem of forest decline demonstrates a precise and effective methodology for determining key problem components and providing solutions. This approach can efficiently identify the particular compounds underlying impacts, including the concentrations, durations of exposure,

and seasonal distribution of these compounds. In addition, the key forest communities and regions at greatest risk in the United States can be determined.

Environmental risk assessments can provide quantitative analyses that include determination of uncertainty and provide expected outcomes of given scenarios of pollutant control. These results could then become a critical component of cost-benefit analyses of various emission control strategies. This approach can provide a way to enhance the management of our nation's resources.

4.5 COMPLEX MIXTURES: ENVIRONMENTAL RISK ASSESSMENT

Environmental risk assessment methods are directly applicable to the problems of complex mixtures. Complex mixtures include effluents and sludges from municipal and industrial sources; dredged materials from rivers, lakes, and estuaries; and stack emissions from industries, power plants, and other sources. Enhancement of environmental risk assessment methods will assist environmental managers in estimating the probabilities and magnitudes of undesired effects that may result from the release of complex wastes into the environment. More effective decisions about technological controls for industrial processes and source modification can thus be made.

Research is needed to enhance the use of environmental risk assessment methods. For instance, analytical chemistry research will yield methods that can better determine the vast array of chemicals in a waste. The research on the interactions of chemicals with solid particles and fluid transport phenomenon will allow more accurate predictions of where the wastes will go once in the environment. Biological research will provide insight into how the various living organisms that may be exposed will react to the mixture. Finally, the enhanced modeling capabilities that will result from this research will present decision-makers with a probabilistic determination of the impact of a complex waste. Then, options can be considered and judgments made to best manage our environmental and fiscal resources.

The potential application of environmental risk assessment methods to solving problems of complex mixtures can be exemplified by an analysis of the alternatives for disposal of sewage sludges. There are various alternatives, such as landfilling, incineration, biological degradation, and ocean disposal, each with its own inherent risks to the environment. *Environmental risk assessment methods can define the probability and magnitude of those risks and provide input into the decision-making process for selection of the most cost-effective and lowest-risk method for disposal of sewage sludges.*

Additional research has been identified which will enhance the risk assessment process for complex mixtures. Some examples of specific research needs are:

1. examination of chronic effects of complex mixtures on aquatic and terrestrial species;
2. determination of the impact of complex mixtures on the transport of chemicals in various environmental compartments; and
3. development of improved methodologies for evaluating the risk of complex mixtures.

4.6 NATURAL RESOURCES CONTAMINATION PROBLEMS: ENVIRONMENTAL RISK ASSESSMENT

The environmental risk assessment process can be applied to many natural resource problems. The benefit of using environmental risk assessment procedures for managing wetlands impacted by multiple stresses is the ability to assess the relative risk for each adverse effect, resulting in a more cost-effective means of allocating resources in order to address the stress which has the greatest risk of causing an adverse impact. This process can also be used to identify which risk measurements contain the most uncertainty and require additional research.

One major problem facing resource managers is the continued loss of wetland habitat because of drainage, urban development, and coastal gas/oil exploration and production. An additional problem is degradation of wetland quality, such as a reduction of submerged aquatic vegetation production because of sediment loading and adverse influences caused by contaminated dredged materials contained in or near wetland areas.

The application of the risk assessment process to a natural resources contamination problem—determining the probability of a dredge disposal site having an adverse effect on given wetlands quality—is exemplified as follows:

Effects Identification

In this example, the first step in the environmental risk assessment process is to determine the toxicity of the constituents identified in the dredged material. If all constituents are known and each constituent has a sound data base of known toxic effects on a wide variety of wetland biota, or if the complex mixture has a sound data base of known effects, the hazard can be calculated by a comparison of exposure and effect concentrations. However, little is usually known about the comparative toxicity of all the constituents to the biota of the wetland, necessitating extrapolation from limited data to a wide variety of species of concern in the wetland. Research is needed to help define the uncertainty with species-to-species extrapolations and to determine toxic interactions of various constituents.

Exposure Evaluation

The next step determines what the exposure concentrations of the dredged material constituents are to wetland biota. Exposure evaluation addresses such issues as the chemical properties of the dredged material constituents under varying conditions of temperature, pH, redox potential, sunlight, and the ability of vegetation and microorganisms to metabolize hazardous compounds. Exposure evaluation also addresses the impact of animal behavior on exposure regime as well as temporal and spatial changes in exposure and pulsed exposures. Research is needed on the bioavailability of toxic constituents sorbed to sediments, absorption/desorption rates for various organics and metals, and rates of transport to enhance the risk assessment process for dredge spoil disposal. It has been clearly shown that bulk chemical analyses do not predict bioavailability. Just because a chemical is present does not mean that it is bioavailable.

Risk Characterization

The last step of the environmental risk assessment procedure is risk characterization. In this step the resource manager reviews the probabilities for risk identified in the previous steps and weighs the estimated risk for potential impact of the disposal practice for all elements of concern. *The risk assessment process affords a sound basis for making this decision by providing a means for identifying the most cost-effective and lowest-risk method of disposing of the dredged material.*

4.7 GROUNDWATER QUALITY: ENVIRONMENTAL RISK ASSESSMENT

Given the importance of groundwater to society, strategies are needed to protect this valuable resource from contamination. The use of environmental risk assessment methods provides a rigorous and sound way of judging the risks and benefits of various management strategies for groundwater.

Groundwater is an important natural resource in the United States, accounting for 95% of the freshwater reserves of this country. Approximately half of the U.S. population relies on groundwater as its sole source of drinking water. This includes most major U.S. cities and virtually all (>95%) of the rural population. Groundwater is also used extensively in agriculture for irrigation purposes, and as processing water for a variety of manufacturing activities.

Each day, thousands of situations arise in which decisions are required to assess the impact of chemical contaminants on groundwater quality. Leachate from municipal and hazardous landfills, leaking underground storage tanks associated with local business and manufacturing activities, effluents from septic tanks, and other on-site wastewater treatment systems represent a few of the situations where environmental risk assessment techniques could guide the decision-making process.

Simulation models could link the chemical concentrations or application rate at the land surface with leaching and runoff rates and, ultimately, to concentrations in groundwater wells and adjacent surface water. Given local data on meteorology, hydrology, hydrogeology, soils, and land use, these models could draw upon a large chemical and biological data base in order to calculate the probability distribution of chemical concentrations throughout the local groundwater and adjacent ponds and streams. Effects models could then evaluate the risks to biota and humans. If the risks are judged unacceptable, the models could be used to investigate the consequences of using different chemicals or control strategies.

Some components of this risk assessment methodology exist today. Other components, however, are undeveloped or need improvement. The simulation models and data bases required for risk assessment must be developed, validated, and packaged into an easily used decision-support system, then rigorously tested under a wide range of conditions. Next, practical utility for aiding various kinds of decisions must be demonstrated. Finally, the software and data bases must be maintained and supported in a credible center of expertise.

Many of these decisions in groundwater quality protection can be categorized and classified into general approaches which in turn could be applied regionally or nationally. Similarly, the data bases (local and national) can aid in many types of problems and their solutions. *Overall, the science and technology of such a data base system are within reach, but a coordinated and intensified thrust from research through development and technology transfer is required in order for such a system to be implemented.*

5.0 SPECIFIC RESEARCH NEEDS IN ENVIRONMENTAL RISK ASSESSMENT

The preceding sections of this report have dealt largely with generic research issues related to environmental risk assessment. Attempts have been made to define the environmental risk assessment process in general, and to indicate the inadequacy of current risk assessment methods for providing a comprehensive basis for environmental decision-making. Several generic examples have shown that improved risk assessment procedures could substantially reduce the uncertainty and improve the scientific basis for decision-making in regard to key environmental problems.

This section identifies specific research needs in several key areas related to environmental risk assessment. This research is critical to the development of comprehensive environmental risk assessments and the use of scientifically based information in the decision-making process.

Research needs in environmental risk assessment can be grouped into several key areas, including risk assessment methodology, aquatic toxicology, terrestrial toxicology, and chemistry, fate, and modeling. Risk assessment methodology primarily involves the assumptions and approaches used to make risk assessments, and therefore can be grouped along functional lines. Research needs in the other disciplines, however, cover a much broader range of areas. In this section, they will be grouped into exposure and effects components, the two key elements in the environmental risk assessment process.

5.1 RISK ASSESSMENT METHODOLOGY

Research needs for improving the methodology and approaches for environmental risk assessments can be divided into seven main categories:

1. Validation of risk assessment procedures.
2. Evaluation of existing risk assessment procedures.
3. Development of risk assessment expert systems.
4. Development of transport, exposure, and effects models for risk assessments.
5. Identification of critical assessment endpoints.
6. Estimation of uncertainty in risk assessments.
7. Communication of the risk assessment process.

Details on each of these research needs, including the environmental issues they address, justification for the proposed research, and a suggested research experimental plan are given in Appendix A.

5.2 AQUATIC TOXICOLOGY

Research needs for improving environmental risk assessment efforts in the area of aquatic toxicology are given below. These needs are grouped into two broad categories, exposure-related needs and effects-related needs, and are listed in order of priority within each category.

Exposure:

1. Bioavailability of chemicals from sediments.
2. Microbial ecology of aquatic ecosystems.
3. Fate and transport of genetically-altered organisms.

Effects:

1. Biochemical/pharmacological/toxicological mechanisms.
2. Prediction of ecosystem stress from controlled laboratory and field investigations.

3. Quantitative structure-activity relationships and physiological/pharmacokinetic models.
4. Identification and measurement of ecosystem stress.
5. Sublethal effects of chemicals in aquatic organisms.
6. Interspecies extrapolation.

Detailed discussions of these needs in aquatic toxicology can be found in Appendix B.

5.3 TERRESTRIAL TOXICOLOGY

Research needs for improving environmental risk assessment efforts in the area of terrestrial toxicology are given below. These needs are grouped into two broad categories, exposure-related needs and effects-related needs, and are listed in order of priority within each category.

Exposure:

1. Exposure evaluation for nonaccumulating and accumulating chemicals.
2. Biotransformation and biological availability of contaminants in the terrestrial environment.
3. Routes of exposure and uptake of chemicals by plants and animals.
4. Factors affecting the exposure of terrestrial organisms to chemical contaminants.
5. Identification of sentinel species.
6. Impact of microorganisms and vegetation on chemical concentrations in soils.
7. Influence of sensory detection on organism exposures.
8. Influence of chemical and biological transformations on exposure.

Effects:

1. Comparative biochemistry and physiology.
2. Sublethal responses.
3. Interspecies extrapolation.
4. Population-level effects.
5. Community-level responses.
6. Behavioral toxicology.
7. Effects of environmental factors on toxicity.
8. Predicting ecosystem effects from chemical concentrations.
9. Toxicity of complex mixtures.
10. Patterns of response related to the duration, frequency, and intensity of exposure.
11. Extrapolation of toxicity data bases to wildlife risk assessments.

Detailed discussions of each of these research needs are included in Appendix C.

5.4 CHEMISTRY, FATE, AND MODELING

Research needs for improving environmental risk assessment efforts in the areas of chemistry, fate, and modeling are given below. These needs are grouped into two broad categories, exposure-related needs and effects-related needs, with specific needs listed in order of priority within each category.

Exposure:

1. Analysis of complex mixtures.
2. Development of computerized chemical data bases.
3. Kinetics of sorption-desorption.
4. Deposition and resuspension of particulate matter.
5. Biodegradation kinetics.
6. Solute transport in fractured media.
7. Atmospheric transport and fate processes.

8. Fate and transport of genetically-altered organisms.
9. Chemical loading.
10. Bioavailability of chemical toxicants.
11. Three-dimensional transport in complex ecosystems.
12. Field validation of exposure models.
13. Probabilistic exposure models.
14. Multimedia transport models.
15. Linkage of exposure and effects models.
16. Development of expert systems for environmental risk assessment.

Effects:

1. Relationships between body burden and toxic effects.
2. Toxicity of metabolites.
3. Toxicity of complex mixtures.
4. Toxicant effects on ecosystems.

Detailed discussions of each of these research needs can be found in Appendix D.

APPENDIX A: RESEARCH NEEDS IN ENVIRONMENTAL RISK ASSESSMENT METHODOLOGY

VALIDATION OF RISK ASSESSMENT PROCEDURES

Research Need

The environmental risk assessment process has yet to be validated. Although decisions are being made daily by industry and regulators about the hazards and risks associated with the release of chemicals into the environment, there has not been a unified, multidisciplinary effort to determine whether the assumptions, criteria, and processes associated with risk assessment decisions are correct. The different approaches currently available for risk assessment, along with new approaches currently being developed, need to be evaluated by both laboratory and field testing.

Issue(s) Addressed

This research provides a fundamental basis for the decision-making process in environmental risk assessment.

Justification for Research

Validation of the environmental risk assessment process would provide numerous benefits to government, industry, and the general public. Since we do not know whether the assessment process currently being utilized to protect the environment is effective, decision-making in both industry and government can be extremely cumbersome and difficult. Lack of knowledge about whether the decisions being made are correct can lead to excessive testing in order to increase confidence or decrease uncertainty, thus draining limited resources away from areas of potentially greater concern. If we do not validate the process, the uncertainty associated with risk assessment decisions will remain high, as will the uncertainty in our knowledge of whether we are adequately protecting the environment. With greater confidence in the risk assessment process, industry will become more effective in making decisions about the production and marketing of new chemicals. In addition, the ability to inform the public about the potential adverse effects of small amounts of chemicals will be enhanced.

Research Plan

Any approach to the validation of current risk assessment procedures needs to involve a multidisciplinary workgroup addressing the question through both small-scale laboratory and large-scale field studies. The major objectives of the validation studies would be to:

1. determine the predictive capability of the specific procedures presently being used;
2. pinpoint or identify the areas of the greatest uncertainty; and
3. identify the relationship between the amount of chemical (fate) and toxicological data available and the resulting uncertainty in the risk assessment decision.

Once the areas of uncertainty are identified, potential methods for reducing the uncertainty could be adopted. Validation should be conducted for a number of chemicals with varying physical/chemical properties. In order to adequately test the sensitivity of the risk assessment process, the chemicals chosen should be of environmental concern and/or represent borderline cases of risk.

A suggested approach (although obviously not the only approach) for validating the process would entail the following:

1. Risk assessment, as it is currently utilized by regulating agencies, should be performed for specific chemicals by using the standard array of toxicological and environmental fate information that would normally be available to either industry or the regulator.
2. After the initial assessment, large-scale field studies should be conducted to determine the fate and effects of the specific chemicals. Subsequent risk assessments will be based on both the critical endpoints identi-

fied in the initial risk assessment and on other endpoints deemed to be ecologically significant. Interpretation of ecological significance will require the field study to be extremely detailed and to entail all trophic levels and trophic-level interactions.

3. After the field study is completed, major areas of uncertainty should be identified. Risk assessments should be made at varying tier levels of the field study and evaluated with respect to uncertainty. Classical hazard assessment theory would predict that the uncertainty should decrease as one includes more sophisticated testing procedures. Appropriate laboratory studies should be designed to provide information on how uncertainty can be reduced for future risk assessments. For example, this may include simply presenting and analyzing the toxicity data in a more useful manner, or completely redesigning the way tests are conducted so that exposure is more representative of real-world conditions.

EVALUATION OF EXISTING RISK ASSESSMENT PROCEDURES

Research Need

A basic principle in research is to build upon and supplement existing knowledge. Before investing additional research funds in risk assessment procedures, a thorough examination of existing procedures and the supporting literature is needed. Reviewing the state of the art will provide insights and understanding of what approaches are now being or have been used, and which of those appear to be most useful in portraying ecological risks. Directions for future efforts can be identified and refined by review of the past and the present.

Issue(s) Addressed

Evaluation of existing risk assessment procedures will identify areas that to date have been weak, point out areas where progress has been made, and indicate areas where further research is needed.

Justification for Research

This type of review will allow researchers to avoid unnecessary duplication and redundancy. It will promote efficient use of research funds by helping to target areas that are inadequately understood at present. The potential results of not reviewing the state of the art are expensive information loss and nonproductive duplication of research efforts.

Research Plan

Research approaches could include:

1. comprehensive worldwide literature searches and reviews;
2. review of existing data bases; and
3. direct communication with government, industry, academic, and private researchers in the field of ecological risk assessment.

Research products (or results) could include:

1. comprehensive reports on current efforts;
2. analyses of areas, parameters, and approaches that work well; and
3. discussions of the trends and directions that state-of-the-art risk assessment procedures appear to be moving toward, and why.

DEVELOPMENT OF RISK ASSESSMENT EXPERT SYSTEMS

Research Need

The need exists to make the best scientific expertise available in the decision-making process for environmental risk assessment of chemicals. The use of expert systems in the risk assessment process can assist us in achieving this goal.

Issue(s) Addressed

This research provides a more informed and efficient basis for the decision-making process in environmental risk assessment.

Justification for Research

This research would facilitate the consistent use of exposure and effects data in environmental risk assessments, thus reducing subjectivity in the decision-making process. It would also allow an easier understanding of how a decision will be made, and ensure that extensive scientific expertise will be behind every risk assessment without need for extensive input of expert judgment. The use of expert systems will also allow the impact of alternative scenarios to be rapidly evaluated, resulting in cost savings in test programs.

Research Plan

A research program to develop expert systems would review appropriate data bases to establish rule-based guidelines (i.e., build "shells"). Qualified specialists would then be required to design expert systems to create a framework for linking assessment models and data bases. Subsequent efforts would bring in experts on environmental toxicology, environmental chemistry, and risk assessment to provide the decision rules and test the utility of expert system in industry and regulatory communities.

DEVELOPMENT OF TRANSPORT, EXPOSURE, AND EFFECTS MODELS FOR RISK ASSESSMENTS

Research Need

Models of the environmental release, transport, and fate of environmental contaminants, the exposure of organisms to contaminants, and the response of organisms to contaminants need to be developed. To be useful, the models must be parameterized with data available to the assessor, must accept and integrate uncertainty estimates, and must provide output that is useful in decision-making.

Issue(s) Addressed

This research provides a more accurate basis for the decision-making process in environmental risk assessment.

Justification of Research

Models provide a means of making the assessor's assumptions explicit and of exploring the consequences of those assumptions. Models of the transport and fate of contaminants in surface water, groundwater, and air are already in common use in environmental assessments. They will need some modification for use in a risk assessment methodology in terms of accepting minimal physical/chemical data and uncertainty estimates. Their primary failing is that they do not serve well as exposure models. Organisms in complex environmental media such as sediment or a forest may have complex patterns of exposure involving processes such as ingesting soil or sediment, breathing soil air, preening, and scavenging carcasses that are not included in existing models.

There are currently no generally accepted or commonly used ecological effects models. Such models are needed to answer the "So what?" questions of environmental toxicology. For example, population effects models could answer the question, "What is the consequence of a 20% reduction in fecundity?" The question might be answered in terms of the probability of local extinction or the probability of reduction of a fishery to the point that harvesting is no longer commercially attractive. Ecosystem models could answer questions such as, "How does reduction in zooplankton productivity translate into reduction in fisheries?" Effects models range from statistical extrapolation models (e.g., correlations between species and life stages) to mathematical simulations.

Research Plan

Modeling studies that would satisfy this need must be integrated into the entire ecological risk assessment methodology. The modelers must ensure that the parameters of their models can be estimated by environmental toxicologists and chemists, or the modelers must provide procedures for converting standard measurements into model parameters. Model linkages, such as between exposure and effects models, must be provided.

Model output must address the appropriate effects assessment endpoints in a readily interpretable form. The output must make clear the total uncertainty in the model output, the sources of uncertainty, and the consequences of uncertainty, including the probabilities of severe effects. The model development program should include a variety of modeling approaches (e.g., both demographic and bioenergetic population models) so that robust conclusions can be reached.

IDENTIFICATION OF CRITICAL EFFECTS ASSESSMENT ENDPOINTS

Research Need

Clear endpoints need to be developed for assessment of environmental effects so that toxicity tests and effects assessment models can be explicitly linked to environmental values that possess public and regulatory significance.

Issue(s) Addressed

If toxicity test data are to be successfully combined with effects models to assess risk, then there must be common assessment endpoints which they jointly address.

Justification for Research

The number of environmental values that might be a risk (e.g., species of organisms, clarity of water, the physical aspect of extensive mature forests) and the ways in those values might be expressed (e.g., harvestable biomass, number of individuals, number of species) are virtually infinite but resources for assessment are not. It is necessary to identify a limited number of critical endpoints for effects assessment. These critical endpoints should be subject to assessment using feasible toxicity tests and effects models, should include valued features of all major ecosystem types, should reflect public values, should be comprehensible to regulators and the public, and should be readily monitored in the environment. Without clearly defined endpoints, testing and modeling effort will be inefficient, assessment will not be comparable, and environmental decisions will be harder to justify.

Research Plan

1. Test systems should be developed that break away from the current traditional approach of single-number endpoints to take account of all data relevant to a particular response in the test organism or population.
2. Ecosystems should be studied to determine those sensitive elements of structure and function whose disruption would lead to significant change and breakdown. This research should describe what constitutes unacceptable change in ecosystems and also identify signals which alert the investigator that such changes are imminent. Research should begin on the key question of determining the mechanisms by which the ecosystem ameliorates stress.
3. Research should explore the means of deriving endpoints for dynamic processes such as production, nutrient cycling, and energy flows.

ESTIMATION OF UNCERTAINTY IN RISK ASSESSMENTS

Research Need

Procedures need to be developed for estimating uncertainty, incorporating it in environmental risk assessments, and conveying it in a useful way to those who make or review decisions.

Issue(s) Addressed

This research provides the basis for the decision-making process in environmental risk assessment.

Justification for Research

This research will help facilitate informed decisions by identifying uncertainty and providing a framework for reducing uncertainty. Benefits of this research include reduction of unnecessary expenditures in research and testing by focusing on key areas with either great or unacceptable levels of uncertainty.

Risk assessment will gain credibility by elucidation of associated uncertainties. Sources of uncertainties include:

1. variances in measurement and testing;
2. extrapolation of data;
3. inherent environmental variability; and
4. model error.

If uncertainty is ignored, research and testing funds will not be efficiently targeted. Unnecessary or irrelevant testing can result, and needed testing may not be done.

Research Plan

To estimate the uncertainty in risk assessments, research approaches should include:

1. statistical analyses of existing data sets;
2. new testing for the purpose of quantifying variances; and
3. development of statistical/mathematical models that examine sources and aggregation of uncertainty.

COMMUNICATION OF THE RISK ASSESSMENT PROCESS

Research Need

There is a continuing need to communicate the environmental risk assessment process to regulators, those regulated, involved professionals, the general public, and elected officials at all levels; furthermore, research into the communication process itself is needed. The challenge is to reduce a very complex process to a simple, understandable, yet informative message that shows each segment of the audience how it is affected by the process. Determination of the human factors in risk recognition and the identification and assessment of values and perceptions related to risk are critical in delivering effective risk assessment methods to users and in structuring the risk communication process.

Issue(s) Addressed

This research provides the basis for informed public discourse about the decision-making process in environmental risk assessment.

Justification of Research

Effective communication of the environmental risk assessment process in terms of how it works and what it means will increase the confidence of each segment of the audience identified above that:

1. individual personal interests are being served;
2. local and national resources are being expended in a rational manner;
3. the environment is being protected; and
4. options are being viewed in the clearest possible light in a consistent and parallel effort to make valid decisions about environmental risks.

Ineffective communication will result in fragmented approaches to environmental risk assessment, possibly leading to misconceptions and unnecessary fears about environmental risks. Needless expense or deprivation of use of resources might result from inadequate or inappropriate risk assessment.

Research Plan

Research on risk communication should investigate public perception of risk to environmental, nonhuman factors, and how best to communicate the concept of risk and the use of the process of environmental risk assessment. Careful attention must be paid to the values of the audiences and their concerns. Efforts should be made to disseminate information about the environmental risk assessment process through means targeted to each segment of an audience. An array of communication devices, ranging from press releases to personal contact to detailed training courses, can be used to inform and educate.

Much of the methodological approach is similar to that now being employed in extension services, but this task also involves acquiring and accessing vast quantities of information in a timely fashion and at a cost affordable to local governments as well as national agencies. It is not enough to have computer programs and data bases: the people capable of delivering and interpreting needed information must be developed into a network that will support a risk communication system.

APPENDIX B: RESEARCH NEEDS IN AQUATIC TOXICOLOGY

DEVELOPMENT OF TECHNIQUES FOR ASSESSING THE BIOAVAILABILITY OF CHEMICALS FROM SEDIMENTS

Research Need

Research is needed to develop techniques to assess the bioavailability of chemicals from sediments. There is a continuing need to better quantify the bioavailability of chemicals adsorbed to sediments and to determine the factors that control bioavailability. We must quantify and eventually predict the biological effects that result from exposure to contaminated sediments.

Issue(s) Addressed

Contaminated sediments in marine and fresh waters are a potential source of pollutants to living resources. Resuspension of contaminated sediments by dredging or natural processes may significantly alter existing chemical equilibria. Present resource losses, both biological (fishery loss from contamination) and nonbiological (port and recreational environments), are significant due to contaminated sediments and should therefore be addressed. The research will complement issues related to FIFRA, TSCA, complex effluents, hazardous waste sites, dredging activities, and management of confined disposal facilities containing dredged materials.

Justification for Research

Quantitative estimates of chemical adsorption/desorption to sediments, bioavailability, and biological effects would provide valuable information about the risk associated with sediment/chemical interactions. Benefits derived would include the recovery of large areas of potentially valuable rivers, lakes, and estuarine harbors. If sediments are a continued source of contaminants, living resources are at risk because of the accumulation of unacceptably high body burdens of specific pollutants.

If this research is not implemented, environmental toxicologists and risk managers will be addressing the mitigation of sediment/chemical problems without adequate technology. Decisions are likely to be delayed because of the uncertainty and valuable resources will remain unavailable.

Research Plan

A series of laboratory and on-site studies should be conducted to determine the bioavailability of sediment-bound contaminants. The sediments evaluated should be collected from ambient waters and should represent different grain sizes, organic content, pollutants, etc.

In addition, a representative suite of epifaunal and infaunal species should be evaluated to detect sediment toxicity (including mutagenic/carcinogenic effects) and chemical uptake under quiescent and resuspended conditions. Results of these laboratory studies should be compared with similar or identical species collected from aquatic systems contaminated with the same sediments used in laboratory tests. The comparisons are crucial in determining the accuracy of the laboratory studies in predicting field effects and associated uncertainties.

MICROBIAL ECOLOGY OF AQUATIC ECOSYSTEMS

Research Need

Research is needed to develop a better understanding of the community interactions, regulation, and metabolism of bacteria, photosynthetic bacteria, algae, protozoa, and fungi.

Issue(s) Addressed

The activity of microbial populations has the potential to reduce the concentration of xenobiotic chemicals to which other aquatic biota are exposed. This research would improve our ability to determine biodegradation rates and estimate chemical exposures. Such information is needed to evaluate the effectiveness of waste disposal site reclamation and the potential impacts of genetically-altered organisms on the aquatic environment.

Justification for Research

Microbial ecology and the population biology of microbial degradation have the potential to reduce the concentrations of xenobiotics in aquatic ecosystems. Bacteria, photosynthetic bacteria, algae, protozoa, and fungi account for a large fraction of net productivity and nutrient cycling in an ecosystem. Failure to understand this major ecosystem component will hamper our understanding of xenobiotic degradation and transformation and make the design of such systems impractical. The effects of xenobiotics on nutrient cycling is poorly understood. In addition, the understanding of microbial systems will make it easier to predict possible ecosystem alterations following the addition of an altered microorganism.

Research Plan

The following areas should be emphasized for further research:

1. population regulation and competitive relationships of microbial communities including consortia;
2. research on the population and community ecology of the eucaryotic microorganisms;
3. anaerobic community structure in sediments;
4. mechanisms of xenobiotic metabolism at the molecular level;
5. bacterial identification and taxonomy; and
6. identification of gene sequences responsible for xenobiotic degradation and the rates movement of these sequences through a microbial community.

FATE AND TRANSPORT OF GENETICALLY-ALTERED ORGANISMS

Research Need

It is critical to understand more clearly the population dynamics and ecology of genetically-altered organisms and their associated gene sequences.

Issues Addressed

This research is needed to address a number of questions concerning the release of genetically-altered organisms into the aquatic environment. The increased use of such organisms to degrade recalcitrant chemicals and for waste site reclamation requires an understanding of the factors that control the survival of these organisms in the environment.

Justification for Research

A new series of questions is being asked in the risk assessment arena. Are altered organisms incorporated into ecosystems and what are the effects? What are the long-term consequences of the introduction of new genetic elements into the environment? How and where do these elements move? The potential utility of such organisms is so large that such organisms will certainly be released on a larger scale in the future. Failure to investigate these questions will cause the risk assessment process to depend on estimates that are often no more than guesses. In addition, organisms can be developed to greatly aid in the biodegradation of hazardous wastes. Understanding the ecological roles of genetically-altered microorganisms should help to make possible the introduction of useful degradative organisms.

Research Plan

Several approaches are suggested for immediate research, which should provide a broad picture of the behavior and effects of genetically-altered organisms in aquatic ecosystems:

1. investigation of the elements that govern survival of introduced organisms and their genetic sequences;
2. rates of vertical and horizontal transmission of genetic material among organisms;
3. investigation of the effects of the genetic background of the organism and the community upon the survival of an introduced element in aquatic ecosystems;
4. the impact of introduced organisms upon the metabolism and function of aquatic ecosystems; and
5. evaluation of techniques for the movement of introduced gene sequences and organisms and the accuracy of the methods in predicting impacts. (Examples include monoclonal antibodies and DNA probes.)

BIOCHEMICAL/PHARMACOLOGICAL/TOXICOLOGICAL MECHANISMS

Research Need

Basic investigations in the biochemical toxicology and pharmacokinetics of aquatic organisms are needed. Research should be undertaken to enhance our existing knowledge of mechanisms of uptake, metabolism, storage, depuration, and mode of action of xenobiotic chemicals and chemical mixtures.

Issue(s) Addressed

This research will address a number of critical problems we currently experience in trying to understand the biological significance of contaminant exposure. Such knowledge is particularly relevant in predicting the potential impacts caused by the release of new chemicals, the discharge of municipal and industrial wastewaters, and the significance of sediment contamination.

Justification for Research

The ultimate benefit of understanding the biochemical toxicology and pharmacokinetics of aquatic organisms is an increased ability to interpret the significance of chemical-induced biochemical, physiological, and histopathological responses, and to relate these responses to the general health and survival of the organism. The understanding of molecular and cellular interactions and resultant modes of action will lead to more qualitative and quantitative predictive techniques and endpoints for:

1. determining the significance of residues in aquatic organisms;
2. measuring and predicting short- and long-term effects;
3. determining effects of intermittent (pulsed) exposures;
4. assessing biological interactions (synergism/antagonism, degradation, toxicity) of chemicals in complex mixtures;
5. diagnosing toxicity, as currently used in human health assessments;
6. performing lab-to-field extrapolations on a biochemical level;
7. increasing an understanding of comparative responses between species; and
8. extrapolating toxic effects among different life stages and sexes.

If this research is not performed, we will not be able to explain modes of action of xenobiotics as well as the disposition, kinetics, and processing of these compounds in aquatic organisms. We will continue to spend large sums of research money on an increasing number of compounds in testing with limited progress towards reducing the error in predicting effects at the organism level.

Research Plan

Use the data base on polynuclear aromatic hydrocarbons and metals as a foundation in assessing the status of this area.

Laboratory:

1. Select representative species from freshwater and saltwater environments. Vertebrates, invertebrates, and aquatic plants where appropriate should be used in research.
2. Identify representative pure compounds and mixtures of environmental relevance with both similar and dissimilar modes of toxic action.
3. Perform tests using a variety of exposures, including constant (short- and long-term) and fluctuating (pulsed) regimes.
4. Determine uptake, storage, metabolism, and depuration.

FATE AND TRANSPORT OF GENETICALLY-ALTERED ORGANISMS

Research Need

It is critical to understand more clearly the population dynamics and ecology of genetically-altered organisms and their associated gene sequences.

Issues Addressed

This research is needed to address a number of questions concerning the release of genetically-altered organisms into the aquatic environment. The increased use of such organisms to degrade recalcitrant chemicals and for waste site reclamation requires an understanding of the factors that control the survival of these organisms in the environment.

Justification for Research

A new series of questions is being asked in the risk assessment arena. Are altered organisms incorporated into ecosystems and what are the effects? What are the long-term consequences of the introduction of new genetic elements into the environment? How and where do these elements move? The potential utility of such organisms is so large that such organisms will certainly be released on a larger scale in the future. Failure to investigate these questions will cause the risk assessment process to depend on estimates that are often no more than guesses. In addition, organisms can be developed to greatly aid in the biodegradation of hazardous wastes. Understanding the ecological roles of genetically-altered microorganisms should help to make possible the introduction of useful degradative organisms.

Research Plan

Several approaches are suggested for immediate research, which should provide a broad picture of the behavior and effects of genetically-altered organisms in aquatic ecosystems:

1. investigation of the elements that govern survival of introduced organisms and their genetic sequences;
2. rates of vertical and horizontal transmission of genetic material among organisms;
3. investigation of the effects of the genetic background of the organism and the community upon the survival of an introduced element in aquatic ecosystems;
4. the impact of introduced organisms upon the metabolism and function of aquatic ecosystems; and
5. evaluation of techniques for the movement of introduced gene sequences and organisms and the accuracy of the methods in predicting impacts. (Examples include monoclonal antibodies and DNA probes.)

BIOCHEMICAL/PHARMACOLOGICAL/TOXICOLOGICAL MECHANISMS

Research Need

Basic investigations in the biochemical toxicology and pharmacokinetics of aquatic organisms are needed. Research should be undertaken to enhance our existing knowledge of mechanisms of uptake, metabolism, storage, depuration, and mode of action of xenobiotic chemicals and chemical mixtures.

Issue(s) Addressed

This research will address a number of critical problems we currently experience in trying to understand the biological significance of contaminant exposure. Such knowledge is particularly relevant in predicting the potential impacts caused by the release of new chemicals, the discharge of municipal and industrial wastewaters, and the significance of sediment contamination.

Justification for Research

The ultimate benefit of understanding the biochemical toxicology and pharmacokinetics of aquatic organisms is an increased ability to interpret the significance of chemical-induced biochemical, physiological, and histopathological responses, and to relate these responses to the general health and survival of the organism. The understanding of molecular and cellular interactions and resultant modes of action will lead to more qualitative and quantitative predictive techniques and endpoints for:

1. determining the significance of residues in aquatic organisms;
2. measuring and predicting short and long-term effects;
3. determining effects of intermittent (pulsed) exposures;
4. assessing biological interactions (synergism/antagonism, degradation, toxicity) of chemicals in complex mixtures;
5. diagnosing toxicity, as currently used in human health assessments;
6. performing lab-to-field extrapolations on a biochemical level;
7. increasing an understanding of comparative responses between species; and
8. extrapolating toxic effects among different life stages and sexes.

If this research is not performed, we will not be able to explain modes of action of xenobiotics as well as the disposition, kinetics, and processing of these compounds in aquatic organisms. We will continue to spend large sums of research money on an increasing number of compounds in testing with limited progress towards reducing the error in predicting effects at the organism level.

Research Plan

Use the data base on polynuclear aromatic hydrocarbons and metals as a foundation in assessing the status of this area.

Laboratory:

1. Select representative species from freshwater and saltwater environments. Vertebrates, invertebrates, and aquatic plants where appropriate should be used in research.
2. Identify representative pure compounds and mixtures of environmental relevance with both similar and dissimilar modes of toxic action.
3. Perform tests using a variety of exposures, including constant (short- and long-term) and fluctuating (pulsed) regimes.
4. Determine uptake, storage, metabolism, and depuration.

5. Document effects at the biochemical, physiological and histopathological levels. Calibrate data collected from different species to reduce the uncertainty associated with variability in responses between species.
6. Collapse these data to address the mode of toxicity.

Field:
1. Repeat pertinent steps above and compare with laboratory results.
2. Quantify the predictability of lab to yield comparisons at the cellular and organizational level.

PREDICTION OF ECOSYSTEM STRESS FROM CONTROLLED LABORATORY AND FIELD INVESTIGATIONS

Research Need

Research is needed to provide a qualitative and quantitative assessment of ecosystem stress induced by chemicals. We currently conduct single-species toxicity tests, microcosm tests, and mesocosm tests to determine the effects and fate of chemicals, but we have not established the relationship of these responses to real-world resource and habitat problems. The proposed research will provide predictive tools from laboratory and field investigations for estimating meaningful ecosystem and community-level responses.

Issue(s) Addressed

This research will address a multitude of environmental contaminant problems and issues of national concern. Specifically, the use of predictive ecosystem tools will be relevant to issues related to FIFRA, TSCA, acid deposition, sediment/chemical interactions, chemical mixtures, and hazardous waste sites.

Justification for Research

Results from this research will provide risk managers with predictive tools for estimating ecological effects and will provide meaningful endpoints for interpreting the ecological significance of chemical residues in aquatic habitats. The following vital questions will be answered by conducting the proposed research:

1. Can interspecific interactions relevant to ecosystem effects be determined in the laboratory?
2. Are there ecosystem functions that can be tested by using single-species tests?
3. What are the physical factors that need to be accurately simulated to provide a sufficiently accurate representation of an aquatic ecosystem?
4. What are the advantages and disadvantages of using microcosms inoculated from the natural ecosystem as opposed to inoculum from laboratory cultures? How predictive are microcosm results of "real world" ecosystem effects?

If this research is not implemented, environmental toxicologists and risk managers will not have the tools needed to conduct adequate risk assessments. We will be addressing environmental problems of the 1990's with technology from the 1980's.

Research Plan

Laboratory and field investigations need to be conducted on chemical compounds with different physical, chemical, and toxicological properties. Meaningful whole-animal, sublethal, and ecological endpoints need to be evaluated in controlled laboratory, microcosm, and mesocosm studies. Factors affecting the toxicity, such as water quality, turbulence, mixing, wind, sediment composition, etc., need to be evaluated in controlled studies. Emphasis should be placed on validating responses in field investigations and specific resource areas to verify the utility of the ecological measurements developed.

QUANTITATIVE STRUCTURE-ACTIVITY RELATIONSHIPS AND PHYSIOLOGICAL/PHARMACOKINETIC MODELS

Research Need

Research is needed to describe the relationships between chemical properties and toxicological endpoints, and to enhance understanding of pharmacological dynamics in aquatic organisms.

Issue(s) Addressed

This research will address a number of regulatory and scientific issues including the prediction of toxicological endpoints, the response to pulsed or time-varying exposures to toxicants, the impact of complex effluents, the frequent need to conduct risk assessments with limited data bases, and predictions of the bioconcentration and biodegradation potential of new chemicals.

Justification for Research

Quantitative structure-activity relationships (QSARs) correlate toxicity test results with other properties of chemicals so that the toxicity of untested chemicals can be predicted. Such relationships are extremely important when risk assessments must be based on limited amounts of data. QSARs also give useful indications about the mode of biological action.

Mathematical models that simulate the physiological action of chemicals provide many of the same benefits, but use basic cellular and physiological parameters. Effects on reproduction, longevity, and behavior may be successfully modeled by these systems. Estimates of predictability and uncertainty should be integral aspects of such models. In addition, such models may be used when policy questions are posed.

Research Plan

Necessary research includes:

1. development of interspecific structure-activity models;
2. development of models for different classes of compounds; and
3. development of generalized physiological models useful for the prediction of physiological responses.

IDENTIFICATION AND MEASUREMENT OF ECOSYSTEM STRESS

Research Need

Measurement and interpretation of aquatic ecosystem health are hampered by a lack of basic understanding of how toxicants affect the dynamics (e.g., interspecies interactions) and functional parameters (e.g., nutrient cycling or spiraling, decomposition, and energy flow) of aquatic systems. Research is required to develop and evaluate meaningful measurements of aquatic ecosystem stress and to assess their accuracy.

Issue(s) Addressed

This research will address a multitude of environmental contaminant problems and related issues of national concern. Specifically, the use of predictive ecosystem tools will be relevant to issues related to FIFRA, TSCA, acid deposition, sediment chemical interactions, chemical mixtures, and hazardous waste sites.

Justification for Research

The outcome of environmental risk assessments can be heavily influenced by the results of field studies; indeed, field studies of aquatic ecosystems are the ultimate measure of toxicant effects. Unfortunately, the interpretation of field studies is hampered by a lack of knowledge concerning the factors controlling aquatic ecosystems and the relative sensitivity of various structural and functional ecosystem parameters. Without additional research in this area, the usefulness and applicability of risk assessment procedures will be limited.

Progress in the identification and measurement of ecosystem stress can address several important environmental issues.

1. What is the sensitivity of ecosystem structural and functional parameters to toxicant stress relative to other commonly measured toxicity endpoints?
2. Are aquatic effects measurements presently used in the risk assessment process adequate for ecosystem protection?
3. How should the results from aquatic field studies be interpreted?
4. What are the uncertainties and limits of extrapolation?
5. How does the sensitivity and resiliency of aquatic ecosystem to toxicant stress vary among different types of ecosystems?

Research Plan

1. Measure and evaluate the relative sensitivity of structural and functional ecosystem parameters to toxicant stress (especially nutrient cycling/spiraling, energy flow, and decomposition), and compare with traditional toxicity endpoints for predictive capability.
2. Determine the primary biological and physico-chemical factors influencing the dynamics of different types of aquatic ecosystems and determine how these are influenced by toxicant stress.
3. Conduct validation studies of proposed measures of ecosystem health by using field studies to assess the predictability and accuracy of ecosystem level endpoints.
4. Determine how pulsed and other time-varying exposure patterns influence the effects of toxicants or aquatic ecosystem.
5. Determine whether any of the proposed measures of ecosystem health can be used in *in situ* toxicity monitoring programs and compare the proposed measures with existing *in situ* measurements.

SUBLETHAL EFFECTS OF CHEMICALS ON AQUATIC ORGANISMS

Research Need

There is a critical need for research to develop or include candidate sublethal indicators of pollutant stress in the laboratory that can be applied readily to the field.

Issue(s) Addressed

Significant sublethal impacts (biochemical, physiological, and behavioral) are likely to occur undetected in natural aquatic systems. The responses (endpoints) commonly measured in traditional laboratory toxicity tests are growth, survival, and reproduction. More sensitive measures of sublethal effects are needed. Sensitive endpoints of chemical exposure can be utilized in FIFRA and TSCA requirements, acid rain investigations, testing of complex mixtures, evaluation of hazardous waste sites, and appraisals of environmental carcinogenesis.

Justification for Research

Recent advances in the fields of physiology, biochemistry, and behavior may provide aquatic toxicologists with sensitive and efficient tools to determine both general and specific sublethal endpoints that equal or exceed the sensitivity of traditional chronic endpoints. The traditional basis used for estimating the effects of a pollutant on aquatic organisms is to determine effects on growth, survival, and reproduction. These chronic toxicity tests are expensive and cannot be conducted on all chemicals and certainly not on all mixtures of chemicals. In addition, these measures are not utilized easily in the field.

Research is needed to establish efficient, cost-effective, sublethal measures of biological effect to detect adverse impacts that equal or exceed the sensitivity of the traditional methods. Without these measures, significant numbers of single chemicals and mixtures will remain untested. With increased pressures on aquatic systems, aquatic ecosystem productivity and stability are likely to diminish. If this research effort succeeds, sensitive measurements could then be made in ambient receiving waters in order to discern significant trends and to evaluate the effectiveness of mitigation or toxicity reduction efforts.

Research Plan

A series of chronic laboratory tests should be conducted with single chemicals on marine and freshwater organisms (that represent most of the species amenable to chronic testing). In addition to established endpoints, behavioral, sublethal biochemical, and physiological measures and histopathologic effects should also be conducted. Candidate measures should include not only those mentioned above, but also those used in mammalian studies to determine modes of toxicity (e.g., carcinogenesis). Specific comparisons of sensitivity must be made between the shorter, more efficient measures of effect to ensure strong correlations with the widely accepted endpoints. Furthermore, some of the new test measurements may be used *in situ* or conducted on organisms collected directly from the receiving water of interest and results compared with those collected from an acceptable control system.

INTERSPECIES EXTRAPOLATION

Research Need

Research needs to be directed into the area of species-to-species extrapolation. The increased understanding of comparative organismal responses in aquatic life forms will lead to (1) increased use of these relationships in broad taxonomic extrapolations between aquatic species and (2) extrapolation between aquatic and mammalian species (in both directions). Additionally, research should be directed towards new aquatic toxicity endpoints such as carcinogenicity, developmental toxicity, neurotoxicity, and immunotoxicity.

Issue(s) Addressed

An improved understanding of species-to-species extrapolation will improve decision-making in a number of important areas, including sediment toxicity, wastewater (effluent) toxicity, hazardous waste sites, recreational water safety and use, and new chemical evaluation/registration.

Justification for Research

Research on aquatic species-to-species extrapolations should be performed to expand the use of data collected for a single species and thus protect additional freshwater and marine life. Research on aquatic-to-mammalian (and mammalian-to-aquatic) species extrapolations can be performed to expand our understanding of mechanisms of toxicity, implement large mammalian data bases in predicting aquatic effects, and use the aquatic species responses in human safety evaluations.

This research will take advantage of fundamental similarities between organisms in order to improve our predictive capability and our ability to extrapolate. At the same time, it will reduce redundancy and costs in testing. The use of new aquatic toxicity endpoints (e.g., neurotoxicity) will also improve our ability to predict sublethal effects and incorporate additional effects measures into risk assessment.

Research on aquatic species-to-species extrapolations should be performed to expand the use of data collected for a single species and thus protect additional freshwater and marine life. Research on aquatic-to-mammalian (and mammalian-to-aquatic) species extrapolations can be performed to expand our understanding of mechanisms of toxicity, implement large mammalian data bases in predicting aquatic effects, and use the aquatic species responses in human safety evaluations.

Research Plan

1. Establish good aquatic organism models: The present need is to focus on a few model species with the intention of expanding the number of models in the future. Examples are:
   a. Traditional aquatic test systems (crustaceans, fish).
   b. Traditional educational/research species (bacteria, aquatic plants, flatworms, hydra, annelids, aquatic insects, amphibians).
2. Improve data base on complex mixtures: An important step will be to expand the knowledge of how aquatic systems respond in complex environmental media.
3. Develop sound validation/evaluation schemes: Validation programs have historically been the subject of much debate. The genetic toxicology testing program carried out by the National Toxicology Program can provide valuable information on failures and successes of validation procedures. We need to establish a protocol for validating and evaluating new aquatic test systems.
4. Identify target areas for use and method of use: Initial discussion should focus on areas where these test systems can be incorporated for aid in risk assessments.
5. Improve techniques for determining exposure: A true quantitative presentation still remains to be worked out in the laboratory. Factors such as dose administered, dose received, and effective dose are currently unavailable in an aquatic system. There has been some effort to provide these data, but much more data are

necessary. Once these variables are accessible, a quantitative relationship can be developed for extrapolation between aquatic species and between aquatic and mammalian species.

6. Determine a means of extrapolating aquatic data: This is a vitally important, but ill-understood area. Quantitative means of dealing with aquatic systems in terms of exposure and extrapolation are needed. Variability caused by inherent differences between species will result in a degree of uncertainty. Extrapolation efforts most include quantitative calibration of responses between species to incorporate the uncertainty in the risk assessment process.
7. Reassess current endpoints: The endpoint is related to the two points discussed above. What types of data are generated? How are these data used? Does the endpoint provide information on potency? Are current safety factors reliable? Can the aquatic test system provide endpoints that will add credibility to our notion of safe exposure concentrations?

APPENDIX C: RESEARCH NEEDS IN TERRESTRIAL TOXICOLOGY

EXPOSURE EVALUATION FOR NONACCUMULATING AND ACCUMULATING CHEMICALS

Research Need

Techniques to evaluate exposure to nonaccumulating and accumulating chemicals need to be developed.

Issue(s) Addressed

A better understanding of the effects of xenobiotics on terrestrial vegetation and wildlife depends upon identification of exposure characteristics of such chemicals. This research will permit a more accurate assessment of exposure to chemicals, thus allowing completion of environmental risk assessments for situations such as pesticide effects on wildlife and air pollution effects on vegetation.

Justification for Research

The accurate determination of exposure is a critical component of hazard evaluation. It is imperative that accurate, sensitive, and reliable techniques be developed for assessing exposure to toxicants in free-living organisms and for making connections between laboratory studies of dose/response and field evaluations of impacts.

Research Plan

The approaches for addressing exposure for accumulating and non-accumulating chemicals are generally quite dissimilar. For accumulating compounds, residue analysis is the chief tool, and considerable advances have been made in analytical methods for this work. However, much refinement is needed to determine the best tissue(s) for analysis for various compounds, differences among species in accumulation pattern, the effects of different dosages/time courses on accumulation, and the effects of simultaneous exposure to more than one toxicant on accumulation. In summary, a good deal of basic comparative toxicokinetic research is needed.

For nonaccumulating compounds, the problem is more difficult. Several approaches that do not rely upon residue analysis are based upon protein (often enzyme) responses to particular compounds. The most successful have been aminolevulinic acid dehydrase inhibition by lead and acetylcholinesterase inhibition by organophosphorus compounds. Additionally, metallothionein (MT) induction by some metals has proved useful, as well as inductions of mixed function oxidase (MFO) component by various organic compounds.

Again, these approaches require considerable refinement, particularly the applicability of MT and MFO inductions to exposure to chemical mixtures. Most of these approaches (excluding acetylcholinesterase) apply to accumulating compounds. Other approaches are needed for important non-accumulation compounds such as rapidly degraded pesticides, manufacturing intermediates, and photochemical air pollutants such as nitrous oxide, sulfur dioxide, and ozone. The applicability of oxidant-mediated responses (e.g., inductions of antioxidant enzyme activities) as indices for exposure of plants, animals, and microbes to these air pollutants, as well as various redox active metals and organic compounds, are now receiving attention and warrant considerable study. Also, indices of exposure to genotoxic compounds merit study. Such indices as DNA unwiding, covalent binding, and micronuclei formation show considerable promise in this area.

BIOTRANSFORMATION AND BIOLOGICAL AVAILABILITY OF CONTAMINANTS IN THE TERRESTRIAL ENVIRONMENT

Research Need

The influence of chemical structure and soil properties on biotransformation and biological availability of contaminants in terrestrial systems needs further research to increase our understanding of the processes involved.

Issue(s) Addressed

Predictive methods are needed for estimating changes through time of soil concentrations of chemicals and availability for uptake by plants and animals. This research has important implications for and applications to fate predictions in surface soils, groundwater contamination, biological monitoring, and selection of remediation strategies at hazardous waste disposal sites.

Justification for Research

The transformation, dissipation, and biological availability of chemicals in soils are governed by the physicochemical properties of the contaminant as well as the properties of the specific soil in which the chemical is found. Establishing the relationships between soil and chemical properties on one hand and biological transformations and availability on the other will enhance the mathematical modeling which is used to predict chemical concentrations through time as well as the uptake by biota at specific sites. This capability will also help to establish concentration goals for cleanup operations, goals which are used to decide when no cleanup is needed, or when to restrict access to a site by humans, domestic animals, or wildlife. These data can also be used to address special problems such as how draining a contaminated pond, applying dredged sediments to land, or damming a river will affect contaminant availability as sediments become soils.

Research Plan

Measure changes in leachability, biotransformation, and biological availability of chemicals using appropriate endpoints under controlled conditions. Experimental variables will include soil properties (e.g., pH, organic carbon content, cation exchange capacity, particle size distribution, texture, moisture content, temperature, nutrient status) and chemical properties (e.g., Kow, Koc, water solubility, vapor pressure, Henry's law constant, molecular connectivity). Evaluate data by using the QSAR approach.

ROUTES OF EXPOSURE AND UPTAKE OF CHEMICALS BY PLANTS AND ANIMALS

Research Need

A better understanding of routes of uptake and the influence of various routes of exposure to some classes of chemicals is needed for animals and plants. Uptake through each of the potential routes of chemical exposure must be quantified and prioritized for several exposure scenarios. The relative rates and importance of each route can then be determined.

Issue(s) Addressed

This research will address the issues of how much chemical actually gets into plants and animals (dose) and what the important routes of uptake are.

Justification for Research

Animals: The actual exposure of nontarget wildlife to chemicals in the field is poorly understood. We do not yet know the important routes of exposure for wild terrestrial animals in sprayed agricultural fields or forest canopies. Current techniques for estimating exposure of wildlife to chemicals rely primarily on extrapolations of vegetative residues to oral (feeding) uptake. This is overly simplistic because many chemicals are readily absorbed through the skin, inhaled, or ingested as a result of preening and/or behavioral interactions. Estimates of actual exposure to chemicals in wildlife will be crude and/or inaccurate until the routes of exposure are better understood.

Plants: The metabolism and translocation of chemicals from leaves to stems to roots (or vice versa) play an important role in the resulting exposure of animals that feed on the plants. Unfortunately, little is known about the relative uptake and/or routes of uptake of chemicals into plants.

Research Plan

Animals: The most promising preliminary approach to studying the effects of various routes of exposure on chemical uptake is laboratory simulations of field exposure conditions. By using laboratory chambers, quantification of the exposure from ingestion, preening, inhalation, and dermal routes can be evaluated. In addition, the effects of varied canopy conditions, environmental factors, and activity budgets (time spent preening, resting, etc.) can be studied under a range of environmental conditions. Later work would compare body burdens of chemicals to uptake prediction by models. A complete quantitative description of the relative importance and rates of uptake via each route of exposure could be developed. The laboratory studies could be followed by field studies in which tracers are used to determine important routes of uptake.

Plants: The uptake of plant segments can be studied by chemical exposure of plants at the root, leaf, or stem, both by aerosols and water routes. The final metabolism, deposition, and availability of chemicals in each plant segment can thus be evaluated.

FACTORS AFFECTING THE EXPOSURE OF TERRESTRIAL ORGANISMS TO CHEMICAL CONTAMINANTS

Research Need

A better understanding of the influence of food, habitat, home range, and behavior on animal exposure to chemical contaminants in terrestrial systems is needed .

Issue(s) Addressed

Animal habitat, range, behavior, and food preference are the primary factors that determine exposure to environmental contaminants. Understanding the relationships between and among these factors is important to the issues of biological monitoring at contaminated sites, design and interpretation of wildlife field studies, and development of a scientifically sound basis for predicting species differences in susceptibility based on exposure.

Justification for Research

This research can provide a scientifically sound basis to:

1. select appropriate species for biological monitoring programs and field tests;
2. predict susceptibility of different species in a contaminated environment based on characteristic patterns of food preference, home range, habitat selection, and behavior (e.g., preening);
3. identify appropriate surrogate species to be used instead of endangered species for field studies;
4. improve overall design of field tests (e.g., number of species, size of plots); and
5. develop methods for extrapolating from studied to unstudied species.

Research Plan

1. Select (or develop) sensitive detection methods (e.g., residue analysis and/or biochemical endpoints) to determine exposure of wild animals to specific chemicals.
2. Establish relationships between exposures and endpoints.
3. Evaluate exposures of various species (including domestic animals) under natural exposure conditions by using these endpoints.
4. Correlate differences in exposure with species-specific characteristics of food, habitat, range, and behavior and with variations of these ecological features within species.
5. Compare species, effects, and effective concentrations of toxicants by using existing data in the literature to relate food, habitat, home range, and behavior to chemical exposures.

IDENTIFICATION OF SENTINEL SPECIES

Research Need

Evaluation of the environmental acceptability of a toxicant requires assessment of its effects over a wide range of plants, animals, and microbes. It is not realistic to monitor all species that are exposed to a substance; therefore, the rational choice of appropriate sentinel species is essential. A sentinel species is a plant, animal, or microbe that can be used as an indicator of exposure or toxicity of a xenobiotic owing to its sensitivity, initial position in the community, likelihood of exposure, or abundance sufficient to allow statistical interpretation.

Issue(s) Addressed

The research will contribute to assessment of the impact of chemicals on the environment, and facilitate biological monitoring and remediation in hazardous waste site investigations.

Justification for Research

Benefits include:

1. an improved ability to protect the natural environment with less financial cost and environmental damage during experimental studies of population responses;
2. the possibility of predicting/estimating effects on species that are themselves too rare or difficult to study; and
3. an improved standardization across studies, thus enhancing comparisons between different areas and allowing greater opportunities for comparing the impacts of different chemicals.

Failure to undertake this work will:

1. impede the understanding of toxicant impacts with possible expensive repercussions for the decision-making processes in waste site cleanup; and
2. cause resources to be spread too thinly across many species, thus diminishing the strength of the resulting data.

Research Plan

For each relevant habitat or system of concern, preliminary surveys need to be conducted to identify the range of species present and the pattern of influx of toxicants. Candidate sentinel species should be chosen on the basis of:

1. abundance;
2. likelihood of exposure;
3. sensitivity;
4. route of exposure (direct or indirect via the food supply); and
5. knowledge of habits/responses to exposure.

Selection can be augmented by laboratory screening of candidate species, which would be improved by basic research to develop novel approaches (such as methods used in cell toxicology) to reveal sensitivity. Choice of species should cover a broad range of taxa, appropriate to the full range of ecosystem components likely to be exposed.

Experimental investigations are needed to explore the utility of indications other than presence/absence to reveal the presence of a toxicant (e.g. behavior abnormalities, biochemical changes, etc.). Validation should involve field studies with monitoring of a range of species in addition to the proposed sentinels.

IMPACT OF MICROORGANISMS AND VEGETATION ON CHEMICAL CONCENTRATIONS IN SOILS

Research Need

Understanding the impact of soil microbial communities and vegetation on chemical concentrations in soils is necessary to determine potential exposure of terrestrial organisms.

Issue(s) Addressed

The major biological factors affecting chemical concentrations in soils are germane to the issues of chemical persistence in surface soils, chemical migration to the subsurface (groundwater), and remediation of hazardous waste sites, spill areas, and other situations where surface soils are contaminated.

Justification for Research

Soil microorganisms provide the major biological mechanism for transformation and degradation of chemicals in soils. Understanding the conditions that favor microbial degradation, including the impact of vegetation (the rhizosphere) on these processes, can provide numerous benefits:

1. Rates of biological degradation in soils can be maximized through site management, including the planting of vegetation.
2. Microbial strains can be developed by using techniques of recombinant DNA and biotechnology to accelerate degradation processes.
3. Properties of soil communities can be developed as biological endpoints to assess the assimilative capacity of soils and their resiliency to chemical impact.
4. Remediation guidance manuals can be developed to specify when vegetative cover should and should not be established at a contaminated site, and to specify which plant species should be used for specific geographic regions, soil conditions, and contaminants of concern.
5. Process information is urgently needed for models of chemodynamics in soils.

Research Plan

Conduct greenhouse, small-plot, and full-scale field studies to measure microbial degradation rates for diverse chemical classes under a variety of conditions. Experimental variables should include presence and absence of vegetation, vegetation type, previous exposure of soil microorganisms to toxicants, contaminant loading rates, and nutrient status of soils. Appropriate controls must be used so that biotic and abiotic transformations can be distinguished.

INFLUENCE OF SENSORY DETECTION ON ORGANISM EXPOSURES

Research Need

Estimates of chemical exposure do not account for the possibility that animals may detect and avoid or be attracted to some chemicals in the field. The impact of the detection of chemicals on exposure is not well understood.

Issue(s) Addressed

The hazard of many chemicals to wildlife in the field may be altered because of the ability of some animals to detect and avoid or be attracted to contaminated fields or foodstuffs. This research addresses the impact of discriminations of chemicals on exposure.

Justification for Research

In order to properly evaluate the exposure to chemicals in risk assessment scenarios, the actual exposure of nontarget wildlife to a chemical must be determined. By using sensory cues, many animals are able to detect and avoid treated foodstuffs if alternative foods are available. It is necessary to understand the mechanisms of detection, the types of chemicals that can (and cannot) be detected, and the impact of these detection mechanisms on exposure. Many field exposure estimates may be modified if we understand the role of behavior on uptake of foodstuffs in treated fields.

If we understand the behavioral and sensory modalities used in the detection of chemicals, we may be able to better estimate the exposure and hazard associated with chemicals in the field. A relative index of hazard can be developed that incorporates not only toxicity but also the potential for discrimination, avoidance, or preference.

Research Plan

Both laboratory and field studies must be conducted to understand the role of discrimination on chemical exposure. In the laboratory, feeding studies with treated and untreated choices should continue. The specific sensory modalities responsible for detection should be identified for several classes of chemicals. The relative ability of various species of animals to detect chemicals should be determined. The relative level of discrimination should be established for several chemicals so that a ranking by potential for detection could be developed. Research studies should include determination of the cues (such as color, texture, smell, and taste) that are being utilized by animals to detect chemicals.

Field studies must be conducted in which the concepts of discrimination developed in the laboratory can be tested for realism. In many field exposures, discrimination abilities demonstrated in the laboratory may not be fully expressed (e.g., for small mammals or invertebrates) because of habitat restrictions, lack of mobility, or other factors.

INFLUENCE OF CHEMICAL AND BIOLOGICAL TRANSFORMATIONS ON EXPOSURE

Research Need

The exact chemical species presented to the organism(s) at risk, as well as the particular species, populations, and communities exposed, will depend on the nature, rate, and extent of transformations of chemicals introduced into the environment. As chemicals move through food webs and between media, these transformations can be critical to the increase or decrease of risk.

Issue(s) Addressed

This research effort is particularly important for predictive toxicology, but will also play an important role in groundwater quality protection, biological monitoring and waste site remediation, and alternative testing methodologies. It enables the pollutant pathways to be described and then quantified, identifies probable effects (by QSAR), and focuses assessment methodologies on the most critical species. This effort is vital to pesticide registration, toxic substances evaluation, and hazardous pollutant assessment.

Justification for Research

Many chemicals are detoxified or otherwise rendered harmless by changes in chemical structure brought about by abiotic and biotic transformations. In a number of cases, the "detoxified" material is not harmless to a consumer or other organisms in the environment. If the metabolite is stored, excreted, or otherwise made bioavailable, it may cause problems. Notable in this regard are some metabolites of DDT (e.g., DDE) and the degradation products of carbamate insecticides (phenols).

Generic methodology for accomplishing the several portions of this need includes: determination of nature and rate of transformation over a range of environmental conditions; presence of constitutive or inducible enzymes capable of carrying out the transformation(s) and the distribution of organisms with these capabilities; the bioactivity of the metabolite, if any; and the means (analytical and biological) of assaying it in diverse media.

If these methods are not available, the risk assessment can be seriously flawed, resulting in unanticipated, severe adverse effects or in excessive regulation, possibly with loss of benefits of the candidate chemical. At present it is not possible to perform assessments without taking these processes into account, but there is no systematic methodology coupled to assessment, particularly beyond a few laboratory species.

Research Plan

The program to accomplish this objective will involve:

1. the development of sensitive bioassay techniques linked to organismic or higher function response and QSAR studies of the gamut of transformation mechanisms;
2. use of tracer (radioactive and/or stable isotope) methods to follow chemicals in organisms and media;
3. characterizations of reactions with respect to responses under differing environmental conditions;
4. modeling of the food webs and other chemodynamic pathways from sources to potential target organisms; and
5. comparative physiology and biology of species with respect to chemical properties.

This work must examine representative chemicals from a broad range of classes as well as a broad spectrum of organisms possessing or lacking transforming abilities. By focusing on functional groups and other properties of the candidate chemicals and by directing efforts to uncover QSAR, new untested chemicals can be evaluated.

COMPARATIVE BIOCHEMISTRY AND PHYSIOLOGY

Research Need

To provide a comprehensive data base encompassing comparative biochemistry and physiology in animals, plants, and microbes.

Issue(s) Addressed

The research has broad application to all aspects of improving our ability to conduct adequate risk assessments for any situation requiring an ecotoxicological evaluation.

Justification for Research

At present, there is a very limited data base on the basic biochemistry and physiology of most nonmammalian organisms of ecotoxicological concern. In contrast to medicine, where clinical decisions are ultimately based upon an extensive body of basic knowledge about the single species in question, ecotoxicological decisions are supported by a generally poor knowledge base of the basic biology of the many potentially affected organisms. Although the proposed research may not directly provide solutions to problems, it is crucial that this information base be developed if ecotoxicology is to advance significantly as a science. Additionally, this research will help determine the applicability of cross-species extrapolations, thus reducing the number of species that must be studied for particular hazard or risk assessments. This research will also help to identify surrogate species that can be used for testing in place of more highly valued ones.

Research Plan

The approaches will vary among organisms (e.g., plant, invertebrate, vertebrate, microbe), but will generally involve the application of methodologies readily available from appropriate, established disciplines (e.g., microbiology, biochemistry, botany, physiology, and zoology). An important consideration here may be a prioritization of organisms that particularly merit scrutiny (e.g., organisms at high risk for exposure, sensitive species, sentinel species, highly valued species, etc.).

Early efforts will involve establishing a data base for selected species on key biochemical and physiological variables of known significance in terms of contaminant metabolism and toxicity. In animals, these variables will include microsomal metabolism, metal and metal-binding protein metabolism, collagen synthesis, endocrine function, immune system function, neurochemistry, and physiology. In plants, key variables include chloroplast metabolism, electron transport and photophosphorylation, auxin metabolism, and stomate function.

SUBLETHAL RESPONSES

Research Need

To determine sublethal biochemical responses (including modes of action) and physiological responses to toxicants in selected organisms, more research will be needed.

Issue(s) Addressed

The research has broad application to all situations requiring ecotoxicological evaluations.

Justification for Research

This research is a logical extension of the program on comparative biochemistry and physiology. A basic understanding of the toxicokinetics, metabolism, modes of action, and critical biochemical and physiological consequences of toxicant exposure in a variety of ecotoxicologically relevant organisms is needed for the development of ecotoxicology as a science. This research will provide innovative techniques for assessing exposure, techniques that are particularly needed for most nonaccumulating chemicals. The elucidation of these responses and an understanding of their relevance to the health of the organism will ultimately be useful in assessing impacts of exposure on populations.

Research Plan

The approaches employed for this research will vary depending upon the particular group of organisms studied and will in large part rely upon existing methodologies available from various disciplines (e.g., microbiology, botany, zoology, biochemistry, molecular biology, genetics, physiology, pharmacology, toxicology). However, considerable care and creativity are required to properly adapt existing methods and/or devise new methods to address the particular compound/organism interaction of interest.

Biochemical responses meriting particular attention include MFO and non-MFO modes of metabolism, free radical-mediated modes of action and response, effects on polyamine metabolism (particularly at early life stages), neurochemical effects, and potentially genotoxic effects (such as covalent bonding to DNA, DNA strand scission, and oncogene activation). Key effects in plants include effects on chloroplast biochemistry and secondary compound production. Important physiological effects in animals which merit study include effects on the immune system, the endocrine system, reproductive physiology, and neurophysiology. In plants, key physiologic effects include effects on reproduction, root tip function, stomate function, and the overall processes of photosynthesis and respiration.

INTERSPECIES EXTRAPOLATION

Research Need

There is a need to increase our ability to perform comparative dose/response data extrapolation and to improve our understanding of scales of extrapolation (for example, species-to-species versus taxon-to-taxon).

Issue(s) Addressed

The need to extrapolate data from routinely-tested species to other species will increase as predictive hazard assessment needs increase. Funds and time, however, will continue to limit expansion of these data sets.

Justification for Research

Decreased research dependence on large numbers of animals is being required by the public through Congress, and this trend is expected to continue. In addition, the current inability to adequately design and fund controlled field experiments necessitates the use of laboratory data to predict potential effects in the field. Research is needed to substantiate and validate the extrapolation process.

Failure to use existing data more effectively will severely reduce the range of risks we can confidently assess and will waste already limited financial and manpower resources. Damage to the environment will continue to increase.

Research Plan

Laboratory dose/response studies should be designed to include a wide range of species and phyla, especially invertebrate and wild mammalian species. The use of LD50 data to predict effects in the field needs to be evaluated and validated. We need to develop criteria for selecting species to be utilized for laboratory and field testing. It will be important to compare test results from pen-reared species to wild species and validate results from pen studies by replicating similar effects in the field. There is a need to develop principles for comparing species that differ in structures, lifestyles, and habitats.

POPULATION-LEVEL EFFECTS

Research Need

Research is needed to assess the feasibility of determining effects of toxicants on populations. EPA and other regulatory agencies currently demand methods for evaluating the responses of animal, plant, and microbe populations to xenobiotics. For field testing, it is essential to determine whether there are approaches that reliably indicate effects on populations. There is an important additional need to explore alternative approaches that circumvent the use of large-scale field testing where such testing can be avoided.

Issue(s) Addressed

This research will not only help to develop methodology for economically providing the data required by regulatory agencies for the registration of new chemicals, but will also aid in protecting and preserving the quality of the natural environment.

Justification for Research

The development of new protocols that indicate effects at the population level will (1) prevent wildlife and plant mortality due to chemical usage; (2) reduce the economic costs of obtaining reliable data for registration purposes; (3) provide evidence of product safety, thereby enhancing manufacturers' international competitiveness; (4) help to avoid potential future environmental problems by identifying compounds which may have population impacts; (5) expand our general knowledge about the population dynamics of species within vulnerable habitats, thus contributing to the success of natural resources management; and (6) facilitate the development of a more complete data base from which to develop computer models allowing extrapolation to other situations.

Failure to address this research need will result in: (1) imposition of unnecessary mortality or other impacts on wild populations during extensive lower-level testing and in the commercial use of products; (2) an increase in the cost of obtaining data for pesticide registration to the point where development of new products or uses may be inhibited, with consequent loss of competitiveness; (3) the unnecessary waste of investment in product development, if inadequate early testing fails to reveal environmental problems that emerge later; and (4) failure to account for hazards to populations in wildlife management strategies.

Research Plan

Basic research studies are needed in a number of areas, including:

Design of Protocols

1. Choice of site should maximize hazard and range of species likely to be exposed.
2. Work should be organized on a regional, not national, level.
3. Environmental chemistry data are needed to define the release and fate of toxicants.
4. Appropriate indicator species should be chosen.
5. Suitable population parameters as endpoints are mortality, productivity, and age-class structure.
6. Replication must allow suitable statistical interpretation. There is a need to explore more sophisticated modes of numerical analysis to maximize the information gained per site and thereby minimize the number of sites necessary.
7. The nature of control data in field trials needs examination, including the relative merits and limitations of before/after comparisons, positive controls, and matched untreated sites.
8. Long-term ecological studies should be initiated to take account of cumulative effects, delayed effects, and recovery of populations.
9. The range of species in wildlife testing should be expanded to include lower vertebrates, plus invertebrates such as earthworms, bees, and other beneficial insects (e.g., predators and parasites of crop pests).

Validation

1. Review the literature on population dynamics to help assess the scale of population reduction from which populations cannot recover.
2. Utilize geographic information systems (GIS) to identify species distributions and vulnerable population/exposure overlaps.
3. Initiate new studies of the population dynamics of selected sentinel and indicator species.
4. Develop improved population dynamics models.

Alternatives to Field Testing

1. Data on population dynamics and the responses to xenobiotics will allow the construction of computer-based models that can be used subsequently to predict effects without recourse to full-scale testing on all occasions.
2. The accuracy of risk assessments at the population level should be checked so that unrecognized hazards can be picked up by undertaking post-registration monitoring of mortality or other endpoints.

COMMUNITY-LEVEL RESPONSES

Research Need

In order to protect ecosystems and their component communities from the impacts of introduced xenobiotics and to establish the broad limits of ecotoxicologic risk assessment, detailed dose-response relationships are needed for such community features as structure and diversity, functional complexity, interspecies interactions, and indicator species of disruption of community function. Furthermore, there is a need to examine the roles of invading or introduced species (whether genetically manipulated by man or not) as a means of understanding ecosystem responses to the introduction of useful species or the deletion of pest species. These basic ecological correlates are critical to the overall ecotoxicologic risk assessment process.

Issue(s) Addressed

This research is critical to biotechnology impact assessments, predictive toxicology, and alternative test methods, and practically useful in all assessments. It has important implications in every field trial; furthermore, as the delimiting consideration in overall ecosystem protection, this research can help to set the basis for protection.

Justification for Research

Community-level responses to stress are the ultimate limitations to the survival of man and the environment. Without clear knowledge of these limits, we may spend very large amounts of money without gaining any extra protection, and we may face serious damage unintentionally or by negligence. There are few clear endpoints in routine use at this level of biological organization, although experience enables us to point out serious damage from failure to consider these interactions. As a basis for understanding much of what is intended by "environmental protection," the studies involved in this methodology will advance ecosystem science while serving as practical guides to decision-making.

Research Plan

A wide variety of research is encompassed in the effort to meet this need. Of particular interest would be those methodologies with functional ecosystem processes in which impacts may be demonstrated, contained or unrestrained field studies, such as pens or open-field evaluations, and laboratory studies of microbial community function. These studies must include pristine, polluted, and recovering communities. The methods employed must be validated against field studies of known manipulations, and the results must be integrated with those from lower levels of biological organization. Interspecies interactions to be studied would include competition, succession, commensalism, predator-prey relationships, parasitism, disease, and facilitation.

Plant relationships and invertebrate relationships are among the features needing broad study with respect to a wide variety of chemicals and biological organizations. Measures of community structure and diversity consistent with dose-response relationships are particularly urgently needed. Identification of sentinel species that exemplify the status of the community and its functions would greatly assist field and laboratory evaluations of toxicant impact, while the impacts on functional relationships would be useful in assessing the role of organismic or population changes within the community. Finally, the significance of responses at the community level must be evaluated with respect to their use as regulatory endpoints and in relation to both higher- and lower-order responses.

BEHAVIORAL TOXICOLOGY

Research Need

Research is needed to increase our understanding of the effects of toxicants on behavior.

Issue(s) Addressed

Sublethal behavioral effects, while difficult to observe in the field under natural conditions, remain an important concern from the standpoint of survival and productivity of species at all levels. The ability to extrapolate from validated, controlled laboratory studies to field situations will therefore remain important.

Justification for Research

No-effect environmental concentrations cannot be readily determined without some knowledge of sublethal but potentially important behavioral effects and their reversibility. Improved understanding of behavioral effects will also allow us to judge the resiliency of individuals under varying exposures and can prove critical in both risk assessment and in making decisions regarding pesticide labeling and use limitations. Many behavioral effects, such as alterations in nest attendance and incubation in birds, may directly affect productivity of populations. Further correlation of behavioral effects with bioindicators such as neurotransmitters and other biogenic amines could eventually decrease our dependence on the large numbers of live animals used in traditional sublethal toxicity studies.

Research Plan

1. Focus the designs of laboratory behavioral studies to measure behaviors that relate directly to reproductive fitness and other population-level endpoints.
2. Validate laboratory studies to at least the semi-controlled field or pen situation.
3. Correlate behavioral effects with other biochemical measures to allow field-level determinations of exposure and hazard by means of these bioindicators.
4. Study the effects of toxicants during critical developmental periods, particularly as they affect those behaviors of the young organism which are critical to its survival (e.g., feeding, predator avoidance).
5. Examine the indirect effects of toxicant-induced behavioral changes (whether negative or compensatory) on aspects of risk assessment, such as the ability to assess mortality in field studies via carcass searching or to changes in activity schedules altered by behavioral responses to toxicants.
6. Examine the indirect effects of toxicants on behavior through influences on the organisms and interspecies chemical ecology, such as interferences with pheremones, allelopathic chemicals, and kairemones. Alterations in the chemical ecology of these systems may influence the distribution of species and thus affect population distribution, community structure, and exposure scenarios.

EFFECTS OF ENVIRONMENTAL FACTORS ON TOXICITY

Research Need

Because toxicity may be altered in field exposures by the influence of environmental factors, research is needed to understand the influence of environmental factors on toxicity of chemicals to terrestrial animals.

Issue(s) Addressed

In many instances, laboratory toxicity data for terrestrial animals may not accurately reflect toxicity in the field. This work will address the question, "What is the impact of environmental stresses on the toxicity of chemicals to organisms?"

Justification for Research

Most toxicity values are generated in a controlled laboratory setting where other environmental stresses are not a factor. However, it is known that the toxicity of chemicals to terrestrial wildlife can be compounded by the addition or interaction of superimposed environmental stresses such as temperature, physiological and nutritional condition, food availability, etc. These factors must be taken into account in any risk assessment that uses toxicity data. The addition of environmental variables into laboratory toxicity tests would strengthen the value of the data and increase the interpretive meaning of the toxicity data for actual field conditions.

Research Plan

Laboratory tests utilized to determine the toxicity of chemicals must be designed to incorporate several key environmental influences such as temperature, physiological and nutritional state, food availability, and behavioral impacts. Various environmental situations could be studied and the most important environmental variables could be ranked and used as appropriate in toxicity tests.

PREDICTING ECOSYSTEM EFFECTS FROM ENVIRONMENTAL RESIDUES

Research Need

There is a critical need to predict effects of chemicals on ecosystems at concentrations well below acute toxicity levels for individual organisms. Interaction between biotic and abiotic components of the ecosystem plays a role in attenuating the impacts of chemicals in the terrestrial ecosystem. Specific attributes to be addressed with respect to the impacts of chemicals on ecosystem level processes include biogeochemical cycling, photoautotrophy, and evaluation and system trajectory.

Issue(s) Addressed

Regulatory language almost always includes a statement to the effect that the objective of that particular environmental regulation is to protect ecosystems and the organisms resident within. In order for policymakers to make a judgment on the potential ecological risks associated with a chemical, they must be able to evaluate the potential damage that may occur to all levels of ecological organization (i.e., organism, population, community, and ecosystem). Issues that need to be addressed using an ecosystem viewpoint include air pollutants such as acid deposition and oxidants and their impacts on ecosystem processes, groundwater contamination and its influence on ecosystem health, hazardous waste site impacts on ecological systems, and the impact of the release of genetically-engineered organisms. In addition, effects on ecosystems have a bearing on predictive toxicology and alternative test systems.

Justification for Research

The ecosystem is composed of a series of complex coupled subsystems that rely on each other for maintenance. A significant change in one subsystem or compartment may have a dramatic effect on another subsystem, which in turn will influence another system. An example of this might be a subtle pollutant-induced change in the rates of nutrient turnover in the soil system. This effect could then cascade to influence the uptake of nutrients by the resident plant community, clearly a significant impact on the insect community serving as the food base for songbirds. Thus, disruption of an ecosystem process might be translated into an indirect effect on another part of the system much later in time. There is clearly a need to determine how chemical or other anthropogenic stressors influence the resistance and resilience of ecological systems.

Concomitant to these stated characteristics is the ability of the ecosystem to inactivate, degrade, or otherwise render the chemical or stressor harmless. There are several examples of this in the literature.

Research Plan

1. Develop computerized ecosystem models that will permit translation of impacts on process-level attributes to other portions of the ecosystem.
2. Further evaluate model ecosystems (i.e., microcosms) to determine the role that they can play in supplying data to perform the risk assessment.
3. Conduct long-term research (including sample banking) to track changes in responses of system processes, community structure and function, and population characteristics with respect to influences of anthropogenic and material stressors.

TOXICITY OF COMPLEX MIXTURES

Research Need

Techniques for assessing the toxicity of complex mixtures of toxicants is required in many environmental situations, including those involving effluents, drainage waters, and dredged materials.

Issue(s) Addressed

Techniques permitting the assessment of toxicity of complex mixtures could be used in a number of situations, including:

1. biological monitoring and remediation in hazardous waste sites,
2. effects of air pollutants on terrestrial vegetation, and
3. effects of pesticides on wildlife populations.

Justification for Research

While the bulk of ecotoxicological research has focused upon single compounds, many key problems involve complex mixtures of chemicals. In terrestrial systems, two critical problems posed by such mixtures are the effects of hazardous waste site leachates on receiving systems and the effects of air pollutants on vegetation. These problems are very difficult to address, but a serious attempt must be made to do so because single-compound studies cannot provide all the information needed for their solution.

Research Plan

This is a broad topic requiring examination of effects at various levels of biological organization. The approaches used will generally follow those described for single compounds; however, instead of single compounds, meaningful assemblages of chemicals (e.g., key PAH's and heavy metals occurring in hazardous waste site leachates or mixtures of nitrous oxide, sulfur dioxide, and ozone reflecting certain air pollution scenarios), as well as "real-world" site-specific mixtures will be employed.

PATTERNS OF RESPONSE RELATED TO THE DURATION, FREQUENCY, AND INTENSITY OF EXPOSURE

Research Need

Toxic effects, including bioaccumulation as an outcome of exposure, are determined by the temporal conditions of exposure, conditions which can be highly variable in real environments (as contrasted to laboratory or other test situations). Methods for predicting outcomes from diverse patterns of such exposures are urgently needed to support risk assessments.

Issue(s) Addressed

This methodology is critical to risk assessments in predictive toxicology, groundwater quality protection, field test validation, atmospheric changes, alternative species testing, biological monitoring, and waste site remediation. Present methods include this type of evaluation only in a limited manner. Commonly used testing reveals only a portion of the temporal relationships, but for certain chemicals the consequences of temporal relationships may be very important for distinguishing between a serious and a negligible risk. Generic knowledge of the relationships by classes of chemicals would considerably enhance predictability.

Justification for Research

Exposures of terrestrial species may be very complex in a temporal sense. Typical exposures can be repetitious, continuous, highly variable, or single (with a declining or steady dose). Bioaccumulation will be markedly different for each type of exposure, and toxic response can similarly vary from no response to a highly significant response, depending on the character of the response and exposure. In order for the computer-generated stochastic concentrations from models of exposure to be used in assessments, the response (both immediate and cumulative) of the test organism must be known. In some cases, this is possible for highly-studied chemicals, but not for new or unstudied agents or environments.

Generic methodology is vital in order to reduce the cost and time of testing and to improve the precision of risk assessments. If this research is not performed, the slow pace of assessments may permit inadequately tested products to enter the market and/or prohibit the use of potentially valuable materials. The absence of such methodology already costs many millions of dollars per year and hinders assessments.

Research Plan

By using a representative range of chemical classes (in terms of structure and properties), various dosing regimes need to be tested with a range of representative organisms from different taxa. These testing regimes would examine the duration of exposure at different exposure concentrations and compare the outcomes with respect to various functions of time and concentration (i.e., median dose, minimum dose, maximum dose, dose interval, and dose frequency). Statistical evaluation and pharmacodynamic models will be used to establish the most appropriate measures of response for different exposure regimes. If these can be characterized and grouped into useful types of response, then the generic application in risk assessments can be validated in field trials. In any event, connection of model simulation of effects to exposure models generating variable concentrations over time will require these analyses.

EXTRAPOLATION OF TOXICITY DATA BASES TO WILDLIFE RISK ASSESSMENTS

Research Need

Improvement in extrapolation of mammalian and aquatic toxicity data bases used in human health assessments, as well as other animal health data bases, will provide more meaningful wildlife risk assessments.

Issue(s) Addressed

Predicting wildlife risk from available information will permit more rapid risk assessment and decrease assessment costs. Wildlife risk assessments could be used for addressing effects of pesticides, industrial compounds, and other xenobiotics.

Justification for Research

The costs and time associated with developing the existing human health and other environmental health data bases cannot be repeated for all wildlife species; therefore, we must decide how to extrapolate from these data bases to wildlife. Efficient and valid use of these existing sources is critical to our effective use of resources, including animal subjects.

Research Plan

1. Compare available rodent-derived human health effect doses with results from similarly-designed wildlife tests, selecting representative species from a variety of taxa.
2. Evaluate the utility of using wild and domestic animal health data bases (e.g., milk and meat testing, disease surveillance, state wild game inspections) to develop predictive models for wildlife risk assessment.
3. Develop guidelines for extrapolation where possible.

APPENDIX D: RESEARCH NEEDS IN CHEMISTRY, FATE, AND MODELING

Research Need

The complexity of the anthropogenic chemical composition of effluents and contaminated natural samples is such that more rapid and sophisticated analytical methodologies must be developed and employed in the formulations of hazard or risk assessments. Otherwise, such assessments will be limited in their accuracy and speed, and hence, their utility.

Issue(s) Addressed

This research will address the broad issue of toxic chemicals in aquatic and terrestrial systems. It will facilitate decision-making relative to discharge permits, monitoring strategies, and cleanup priorities, and will assist in toxicological evaluations of complex waste sites.

Justification for Research

Much of the analytical chemistry that has been performed on environmental samples has focused on identifying and quantifying a preselected group of compounds. Other substances are often ignored, even though detected, or they are intentionally removed from the extract during the cleanup process to make the analysis simpler. These omissions can influence the accuracy of environmental hazard and/or risk assessments.

There are several benefits that will result from research in this area. One will be that toxicologists will be better able to assess or predict the biological impacts from the total loading of toxicants to, or in, the system in question. Another benefit will be that mathematical models will be formulated which will take into account the interactions of chemicals and how those interactions influence the transport and fate of chemicals in ecosystems.

Research Plan

Modern instrumentation, when coupled with computers, offers the potential to alleviate many analytical difficulties. One of the most powerful combinations for the analysis of organic substances consists of a computer coupled with a gas chromatograph (GC) and a mass spectrometer (MS). Much of the strength of this analytical system is based on the high specificity of mass spectra, combined with an index that defines the position of a compound in a gas chromatogram. The role of the computer is to keep an accurate record of the raw data input and to process these data in the shortest possible time into an intelligible array of results. For the aromatic fractions of sample extracts, the definition of a precise gas chromatographic retention index is of utmost importance.

The high resolution of capillary columns, combined with the high precision of retention indices (RIs) and the specificity of mass spectrometric information, reduces chemical laboratory work. More important, the RIs act as an independent parameter to tentatively identify a compound, to perform a reverse search of MS data, to retrieve information from a data bank, or to correlate data from separate gas chromatographic injections.

There are other new and promising instrumental combinations that are emerging. These combinations allow more detailed analyses of certain classes of compounds which, until now, have received little attention (i.e., polar metabolites of polynuclear aromatic hydrocarbons). Such combinations include gas chromatography/infrared spectroscopy/mass spectrometry, gas chromatography/supercritical fluid liquid chromatography, and high performance liquid chromatography/mass spectrometry.

A research program should be initiated to compare the precision and accuracy of various existing organic analytical methodologies in determining the total qualitative and quantitative content of environmental samples. The program should then focus on combining the best aspects of each to develop an optimum system. Further, the program should identify specific research needed to refine and upgrade the methodology.

The analytical chemical research program should also investigate the potential of determining the chemical speciation (i.e., complexed, chelated, ion pair, etc.) within the sample. This is important because the chemical speciation often determines the route, rate, bioavailability, and effect of a chemical.

DEVELOPMENT OF COMPUTERIZED CHEMICAL DATA BASES

Research Need

Chemical analyses of environmental samples are generating ever-increasing amounts of data. Additionally, with the relatively recent emphasis on environmental mathematical models, more fate and transport parameters are being quantified. Because these data should be available to all investigators, there is a need to generate a system to allow the efficient transfer of information.

Issue(s) Addressed

This research will address the broad issue of toxic chemicals in the environment. It will also assist in mathematical modeling of the transport, fate, and resulting biological effects of chemical toxicants in ecosystems.

Justification for Research

Numerous investigators in academic, governmental, and industrial institutions are analyzing environmental samples for chemical contaminants and are generating vast amounts of data. Unfortunately, most of these data remain within the confines of the particular institution. Researchers are also identifying and quantifying various physical and chemical parameters that are essential in formulating transfer coefficients for mathematical models. Often these parameters are unavailable to the scientific community at large.

A computerized data base system that can collect and store such information and allow open access by qualified researchers would greatly assist in formulating models used in hazard and risk assessments. If this research is not performed and such a data base system is not developed, we will continue to fail to utilize the majority of our chemical data. We will also duplicate determinations, thus wasting time and money.

Research Plan

There are several data base systems in existence, but they were not designed to handle the large amount of chemical information that is now being generated. For instance, STORET is not capable of accepting the mass spectra of the many unknown or unidentified compounds in an environmental sample. Although existing data sets/libraries should be utilized when they meet a particular need, it is essential that a new system be developed to accommodate the new demands.

One approach to solving this problem would be to convene a workshop of environmental analytical chemists and modelers to assess the present state of the art in computerized data systems. Such a group could recommend experiments which could be conducted to determine the feasibility of direct coupling of individual instrumental data systems to a large central computer or to determine how data could be transferred via disk or tape. Requests for proposals focusing on such research needs could then be issued.

Paramount to establishing any such data base system is the use of Standard Reference Materials (SRMs) in chemical analyses to ensure accuracy. At present there are few environmental SRMs that represent the true matrix in which chemical contaminations exist or contain all of the isomers of interest (e.g., chlorinated dioxins or PCBs). Research and funding should be directed toward this problem.

KINETICS OF SORPTION-DESORPTION

Research Need

The behavior of toxic chemicals in the environment is determined in large part by their sorption-desorption mechanisms. Knowledge of the kinetics of sorption and desorption is basic to understanding and predicting the effect of these toxic chemicals on the ecosystem, and indeed is basic to all other studies of environmental toxicology.

Issue(s) Addressed

The movement of chemicals from one medium to another by sorption-desorption is a factor in many environmental issues, from acid rain to cleanup of hazardous waste sites. The simple knowledge that a toxic chemical is present in the environment is not enough. In order to know whether or not a chemical will have an undesirable effect, we must know how much of it is available to the ecosystem in a form that can produce an adverse effect. Modern analytical techniques can tell us that a toxic material is present, even when it is present in ultratrace amounts. But these techniques do *not* tell us how *the material reacts* when associated with various soils, sediments, or solvents. Knowledge of the sorption-desorption behavior is necessary for predicting movement of toxic chemicals in aquatic, terrestrial, and atmospheric media, and for assessing what this movement is likely to mean to the ecosystem.

Justification for Research

A large body of knowledge is available on equilibrium sorption. However, much less information is available regarding the kinetics of sorption. Observed equilibrium hysteresis and the long desorption time found in some laboratory kinetic studies suggest that kinetic rates may be a controlling parameter in natural systems. Sorption-desorption kinetics are one of the most important parameters one must have in order to answer the following questions:

1. Will the substance move in the environment? How fast? Under what conditions? How far?
2. At the concentrations found, is the substance likely to become biochemically available in amounts sufficient to produce an effect? Under what conditions?
3. If an undesirable effect is predicted, what kind of mitigation strategy is called for?
   a. Stabilization *in situ*?
   b. Treatment *in situ*?
   c. Removal and treatment?

Not having answers to these questions could result in mitigation responses being ineffective or more expensive than necessary. Without adequate sorption-desorption data, the most cost-effective solutions to contamination and cleanup problems will not be made.

Research Plan

A variety of research approaches should be employed. These include:

1. the determination of sorption desorption kinetics for various classes of chemicals (i.e., polar, ionic, organic, metals, etc.);
2. the effects of various types of particles and substrates on sorption-desorption (e.g., mineral grains, biological films, plankton, etc.); and
3. the effects of natural organics (humics and fulvics) on sorption-desorption. This would include determining whether there are differences in movement when the material is living rather than nonliving, a factor which could be especially important in heavily contaminated areas where the contaminant is a primary energy source for microorganisms.

DEPOSITION AND RESUSPENSION OF PARTICULATE MATTER

Research Need

There is a need to quantify the processes controlling the transport and fate of the various types of particulate matter (bottom, suspended, biotic, and abiotic) and their role in the transport and fate of toxic chemicals because of the propensity of many chemicals (most organics and trace metals) to sorb to these solids. The mechanisms involved in phenomena such as resuspension (e.g., bed failure of cohesive sediments) and deposition (e.g., flocculation and or fecal pellets) need to be understood. The importance of bacteria and plankton generation in the transport and fate of the chemicals is largely unknown. Sediment processes such as bioturbation and sedimentation must be better quantified. This research is needed to provide more accurate estimates of sediment-chemical transport parameters.

Issue(s) Addressed

Research in the area of deposition-resuspension will address several key environmental issues, including waste load allocation of toxicants, impacts of dredging operations, persistence following waste cleanup, pesticide exposure analysis, chemical exposure analysis, and deep ocean disposal of wastes (organic, inorganic, radioactive).

Justification for Research

A key benefit from this research would be more accurate predictions of the transport, persistence, fate, and biological effects of toxicants, particularly for hydrophobic organics and metals. These chemicals will concentrate where sediments are trapped in estuaries, lakes, reservoirs, and stagnant areas in rivers. These chemicals may also persist in the bottom sediments long after the source has been regulated, perhaps leading to long-term chronic exposure. Sediments may increase or decrease the reactivity of chemicals, and finally, sediments may also modify the biological effects of these chemicals.

The result of not doing this research would be either the expensive requirement of collecting large amounts of sediment field data for each site-specific assessment, or the potentially costly acceptance of more uncertainty in predicting chemical fate, persistence, and biological effects.

Research Plan

Sediment research would benefit from a combination of lab, flume, and field studies. Lab and flume studies could best quantify the variables and processes controlling aggregation, consolidation or failure of cohesive sediments. These relationships must be extrapolated and validated in field studies. Correlations between easily measured properties (size fractions, clay type, organic content, salinity) and shear-strength profiles must be developed. Relationships between turbulence levels, sediment size, density, and type and deposition rates (or velocities) should be developed and tested. Relationships between benthic organism type and density and bioturbation must be developed and tested.

BIODEGRADATION KINETICS

Research Need

The major cycling mechanism of carbon in any ecosystem is biodegradation. This important research area is poorly defined and understood. With the extensive use of xenobiotic chemicals, it is important that better degradation models be developed and validated.

Issue(s) Addressed

Biodegradation research is needed to determine the fate of chemicals in a number of key compartments, including subsurface/groundwater, terrestrial (soil) environments, lakes, rivers, and estuaries.

Justification for Research

Biodegradation of organic chemicals is the most dominant removal mechanism operating in the environment can decrease the exposure potential to sensitive biota. Processes such as photodegradation and hydrolysis have generally been shown to be far less likely to remove chemicals from a given environment and often result in incomplete degradation; thus, they are ineffective in removing chemical mass. Further research will enhance our ability to predict exposures of aquatic and terrestrial organisms.

Biodegradation plays the key role in removing chemicals in the subsurface. Therefore, it is critical to understand biologically mediated loss rates in order to predict concentrations of contaminants in groundwater for homes and communities that use groundwater as a source of drinking water. Without this information, predicted concentrations may be unrealistically high (assuming biodegradation is not included in the predictive model) or highly uncertain because environmental biodegradation is not well understood in a number of environments.

Further research will also result in assay systems that can be used to access biodegradation of new chemicals which may be introduced into the subsurface. These materials may degrade slowly, but such slow rates, which would not be detected by present assays, may be sufficient to remove the chemical before it reaches a drinking water source.

Research Plan

Several approaches are needed to address this broad area:

1. Determine the range of pseudo first-order rate constants for chemical transformation in similar environments (e.g., surface waters). These rate constants are applicable to probability based models and may sufficiently define most environments.
2. Determine the effect of temperature and nutrients on pseudo first-order rate constants.
3. Determine the importance of using second-order relationships which include the system biomass. Biomass determination would be done using a chemical-specific procedure such as a most probable number (MPN) determination.
4. Determine the effect, through laboratory and field studies, of non-oxygen electron acceptors on biodegradation rates in the subsurface. Conduct field transects to determine the variation in rate constants.
5. Integrated biological rate expressions that include the data collected above should be formulated for the environmental compartment of interest (e.g., unsaturated zone of the subsurface).
6. Chemicals often exist in the environment in a bound form (complexes, sorbed), yet are free in solution. Appropriate assays to determine the effect of binding on biodegradation rates should be conducted.

SOLUTE TRANSPORT IN FRACTURED MEDIA

Research Need

The development of modeling methods to handle the transport of toxicants in highly fractured, heterogeneous media is needed because significant uncertainty exists in predicting the rate of migration and the concentration of chemicals moving through such media. These uncertainties can contribute to underestimates of the exposure due to contamination of drinking water sources.

Issue(s) Addressed

Contamination of groundwater aquifers that serve as drinking water sources can result from application of pesticides, from chemical spills, and from leaching from waste sites. Present methods are limited in their ability to quantify the risks posed by these activities because of the heterogeneous nature of the underlying strata and the channeling effects that can occur as a result of fractured media.

Justification for Research

Without adequate methods to model heterogeneous and fractured media, we are unable to make accurate predictions of potential groundwater contamination in many areas where these conditions exist. Numerous examples can be found in the literature where contamination of drinking water sources has occurred that would not have been predicted, but which can be attributed to the existence of fractured media.

Research Plan

Case studies of groundwater contamination incidents need to be compiled and examined to quantify how frequently fractured media have contributed to contamination of aquifers. Geological maps that identify areas where fractured media are prevalent need to be compiled for use in conducting risk assessments. Improved mathematical formulations need to be developed and incorporated into existing groundwater models to more accurately model fractured flow. Field testing of these improved models needs to be undertaken.

ATMOSPHERIC TRANSPORT AND FATE PROCESSES

Research Need

Knowledge of atmospheric transport and fate processes is important in the evaluation of animal, human, and plant exposures from chemical deposition and partitioning. This knowledge is also needed for assessing the impact of natural and anthropogenic chemicals (e.g., chloro/fluorocarbons and carbon dioxide) on the atmosphere.

Issue(s) Addressed

The distribution of chemicals from a cropland, waste site, or other source into the atmosphere, and the potential transport of these chemicals to nontarget environments and organisms, are important parameters in determining environmental risk. One important issue to be addressed is the potential reduction of stratospheric ozone by chloro/fluorocarbons (CFCs) with a resultant increase in ultraviolet radiation. A related issue involves the increase in atmospheric carbon dioxide that causes additional terrestrial heat storage.

Justification for Research

Atmospheric transport is a major pathway in the distribution of pesticides after crop spraying, in the distribution of various chemicals via fugitive emissions, and in the distribution of hydrogen ions (acid precipitation). Vapor transport and vapor decomposition rates are particularly important in the case of highly hydrophobic materials. Such materials travel in aerosols. If they are stable (not biodegradable), this is a major route of transport.

The use of incineration is increasing, as are atmospheric inputs from landfills, hazardous waste disposal, and industrial effluents. Research is needed to determine local and global atmospheric concentrations of chemicals that can exert toxicity through inhalation and deposition to the land surface. In addition, research is needed to refine our understanding of the phase distribution of chemicals (i.e., gaseous, dissolved in water droplets, particulate) in the atmosphere. Without this research it will be impossible to understand the source strengths, phase distribution, and influences of weather on atmospheric chemical concentrations. It is vital to understand these phenomena in order to reduce exposure to populations.

Both the terrestrial and aquatic environments can be affected by atmospheric deposition. Further understanding of wet deposition and dry deposition velocities to water bodies, plant surfaces, and soil is needed. Without this additional research, it will be difficult to link effects data on aquatic and terrestrial biota (e.g., crops, forests) to atmospheric concentrations.

Another area of concern requiring further research is the interaction between the atmosphere and bulk water at the air/water interface. Aqueous exposure and effects in waterbodies are often driven by atmospheric concentrations. This is the case for PCBs in Lake Superior, for instance. Without a further understanding of adsorption/volatilization, Henry's Law, and liquid mass transfer coefficients, it will be difficult to accurately predict aqueous exposure concentrations for volatile (e.g., trihalomethanes) and semi-volatile (e.g., PCBs) compounds.

Research Plan

Research in the following areas is needed to address atmospheric transport and fate processes:

1. Atmospheric loading rates should continue to be determined by using air sampling and precipitation networks. The technology of these devices should be improved to make them as usable and realistic as possible (e.g., the desorption of organic compounds from particle traps should be prevented).
2. Predictions of atmosphere concentrations and deposition via air sampling/precipitation networks should be correlated to chemical use, physical/chemical properties, and dominant weather patterns. Efforts should be made to improve measurements of dry deposition velocities, and assessment of the relative contribution of wet and dry deposition to overall atmosphere fluxes should be encouraged.

3. Chemicals that volatilize from landfills may represent a significant contaminant to the atmosphere (e.g., trihalomethanes, PCBs). Air phase fluxes from landfills should be measured and correlated to atmospheric concentrations and loading rates in precipitation.
4. Adsorption/volatilization fluxes to and from water bodies need to be correlated to environmental parameters such as wind speed and water temperature. Models to calculate vapor phase and aqueous concentrations should continue to be developed as well as efficient techniques to measure these concentrations.
5. Key chemical species measured in the stratosphere do not always correspond to model predictions. There is a need to improve chemical models for stratospheric composition.
6. For risk assessment purposes it is essential that chemistry models be linked to global circulation and climatic models. This will facilitate the correlation of ozone depletion and carbon dioxide increases with longitude and latitude. These geographical exposure predictions should be linked to effects data on cash crops and terrestrial/aquatic biota to complete the risk assessment.

FATE AND TRANSPORT OF GENETICALLY-ALTERED ORGANISMS

Research Need

Basic techniques need to be developed to track genetic information through various environmental compartments. These bioassays should be straightforward, inexpensive, and linked to other bioassay data sets in compartmentalized fate and transport models.

Issue(s) Addressed

The release of genetically-altered organisms, especially genetically-engineered microorganisms (GEMs), is both a scientific issue (the inherent environmental risk to the total gene pool of the biosphere) and a socioeconomic issue (cost/benefits of new products and markets versus the potential effects of human exposure).

Justification for Research

Historically, natural organisms have undergone significant modification via genetic selection without significant risk in both industrial and agricultural applications. However, the risks associated with artificial insertion of genetic information and the subsequent release of this sequence into the environment are unknown.

The potential benefits from a human health-effects perspective are also significant. The entrance of genetic information into the human ecosystem is currently unknown and only marginally quantifiable. Clearly, such genetic manipulation is the focal point of an emerging technology. Documenting the safety of this emerging technology and establishing proper safeguards with respect to possible vulnerability to the global gene pool is critical to further research and development, promotion, and marketing.

The possible consequences of not conducting basic bioassay research in this area are many. However, two major concerns are apparent: (1) How will scientists clearly be able to evaluate risk and damage to the human ecosystem should an accidental release occur?, and (2) recognizing the benefits derived from genetic selection, how will scientists quantitatively determine when a needed product or formulation can be safely utilized?

Research Plan

As a suggested research approach, an example using a microorganism is presented:

1. Incorporate standardized GEMs into accepted microcosm approaches, for evaluation of the potential for transposing genetic information. The GEMs selected should be relevant for documenting risk factors to public health, agriculture and the aquatic ecosystem. *E. coli* should not be the only standard.
2. Interlaboratory testing of candidate GEMs and standardized GEMs should be completed. Preferably an industry laboratory would complete the initial research followed by independent testing in a university laboratory. Final testing and documentation for field testing could be completed at a federal laboratory.
3. Mesocosm scale experiments, i.e., controlled field or greenhouse release experiments, would then be conducted to validate laboratory assays and approaches.
4. With respect to microbial ecology, issues such as transposability of genetic information, survivability of candidate GEMs, GEM field performance, and environmental risks to field personnel, fauna, and flora need to be addressed.
5. A final outcome of such research would be development and testing of mathematical models of microorganism growth, death, and gene transfer in natural environments.

CHEMICAL LOADING

Research Need

There is a need to better understand and quantify the probability, magnitude, and duration of chemical loading events from potentially important sources such as manufacturing, transport, storage, and disposal facilities.

Issue(s) Addressed

Research on chemical loading is important to estimate exposures from manufacturing, in particular from land disposal and waste disposal facilities, and from the deep ocean dumping of wastes (organic, inorganic, and radioactive).

Justification for Research

Often the most poorly characterized component of exposure calculations is chemical loading. This research should help us to more completely and accurately estimate the risks posed by particular chemicals or by particular facility designs. The result of not doing this research would be either to allow a large source of uncertainty to remain in exposure and risk assessments, or worse, to underestimate the true risks posed by a chemical or a technology.

Research Plan

The research to quantify chemical loading will vary with the potential source. Two approaches are to use fault-tree analyses and historical analyses of accidents. These should better describe the probabilities, magnitudes, durations, and intensities of accidental discharges such as leaks, spills, and emissions from various types of facilities (manufacturing, storage, transport, and disposal). Statistical sampling of land disposal facilities should provide a range of key properties such as size, type, proximity to streams, soil and geologic data, status of engineering controls, location in and size of watershed, and local hydrology. Research to better characterize the distribution of chemicals in various waste streams would also be helpful.

BIOAVAILABILITY OF CHEMICAL TOXICANTS

Research Need

The presence of a chemical in the environment does not necessarily mean that the chemical will be taken up by the biota. An understanding is needed of what governs the biological availability of chemical toxicants in order to better assess the hazard and risk of the substances.

Issue(s) Addressed

This research will address the broad issue of potential damage to the ecosystem by toxic chemicals in the environment. Specifically, this research will be crucial to making decisions about discharge permits, hazardous landfills, and cleanup options.

Justification for Research

Laboratory tests are often conducted under conditions that may not realistically approximate the r ural environment. For instance, larval bioassays are usually performed with filtered water to reduce problems with particulate matter and bacteria. This may result in the tested chemical not partitioning to the solid substrates as it would in nature. Research is needed to relate laboratory tests to biological availability in the environment.

The influence of environmental factors on the chemical speciation or physical phase of a substance (i.e., salinity and Cd Cl^{-} concentration) can be extremely important in determining biological availability of that substance. Often, chemical speciation and physical phase are ignored with respect to bioavailability. This results in errors in risk or hazard predictions. Furthermore, octanol-water-partition-coefficient models developed in the laboratory may not reflect what occurs in nature; for example, the uptake of chlorinated hydrocarbons by fish gills may not be from the material dissolved in water, but from particles in which the material is sorbed. Therefore, sorption kinetics are important parameters which should be experimentally verified.

Research Plan

Research to validate bioconcentration factors derived in laboratory, microcosm, and/or mesocosm experiments needs to be performed. A recommended approach is to compare existing chemical concentrations derived from actual contamination events with laboratory-derived predictions. Research is also needed to explain why some species concentrate chemicals mainly from food while others do so mainly from solution.

THREE-DIMENSIONAL TRANSPORT IN COMPLEX ECOSYSTEMS

Research Need

More research is needed to better quantify water circulation patterns in complex systems such as stratified reservoirs, estuaries, coastal seas, and deep oceans, especially where three-dimensional transport patterns, residual circulation, and fronts play an important role.

Issue(s) Addressed

Research in this area will lead to better waste load allocation in stratified or partially mixed estuaries, safer dredging and disposal in complex estuaries, and safer ocean disposal of toxic chemicals and radioactive wastes.

Justification for Research

In some bodies of water, circulation patterns are both very complex and somewhat uncertain. Stratified or partially mixed reservoirs, estuaries, coastal seas, and deep oceans are particularly difficult cases. Estuaries and coastal waters can contain crucial habitats for important species. Predicting average concentrations with net-flow calculations may be misleading when residual currents can lead to "hot spots" in sensitive areas.

The result of not doing research in this area would be to underestimate the risks of chemicals in complex bodies of water, or to require intensive—and expensive—site-specific monitoring for these cases.

Research Plan

Research should first identify the best candidate circulation models and evaluate their completeness, efficiency, and ease-of-use. Good hydrodynamic monitoring data sets should be identified and augmented if possible. Further development of monitoring and modeling techniques may be necessary for efficient calibration and use of the models.

FIELD VALIDATION OF EXPOSURE MODELS

Research Need

Decision-makers in all areas of environmental risk assessment and management must assess the validity of research based upon reliable data. Field validation of models is needed to provide evidence that model predictions in various environments are credible. Our lack of knowledge concerning the quality of existing modeling frameworks necessitates further research. Development of cost-effective laboratory data that are useful in field predictions is also needed.

Issue(s) Addressed

Research in this area will be central to understanding risk assessment effects in a variety of environments (e.g., groundwater, surface water, estuaries), and useful in defining waste load allocations.

Justification for Research

The prediction of environmental concentrations is an important element of hazard and risk assessment because it is not possible to extensively monitor every environment of interest. Model predictions depend on a number of assumptions that can be both theoretical and empirical. Any assessment of the adequacy of models requires that they not only reproduce what has been observed, but also forecast responses to changes in input. It is therefore essential that data be developed to validate model predictions. Without this information, there can be little confidence in predicted concentrations, making regulation of chemicals less certain while also increasing the overall cost. Judicious validation is cost-effective because a valid model can often be used in place of expensive monitoring studies.

The ultimate evaluation of a model is the "post-audit." Was the model's prediction accurate? The appraisal of a model in a post-audit allows a critical evaluation of the assumptions and simplifications implicit in the models formulation. Through this evaluation, research needs may be formulated.

Laboratory-to-field extrapolation is also important. For example, these data are important components of predictive model rate coefficients (e.g., biodegradation constants). Realistic exposure and effects data are key elements in developing accurate risk assessments. It is extremely difficult to perform testing in the field; extrapolating meaningful comparative (lab-to-field) data is a cost-effective tool in developing risk assessments. Predictions based on these laboratory data can then be validated through selective field monitoring.

Research Plan

Research in model validation should include the following:

1. Validation should accompany any new use of a model.
2. Existing data (e.g., STORET) can be used for model validation; however, research is needed to determine which chemicals are good surrogates if data for the chemical of interest are unavailable.
3. Work is needed to determine the frequency of data collection needed for effective model validation. It is also important to determine the degree of accuracy and the type of data needed to validate a particular model that is being used for a given purpose.
4. The lack of comprehensive long-term field data bases has precluded post-auditing of toxics models. It is critical that such data be obtained. As a starting point, synoptic field studies should be conducted for problem contexts in which model calibrations and predictions have already been made.
5. Extrapolation from one environmental compartment or location to another is important, and parameters should be determined in each experiment to allow this to be done. For example, rate constants determined in the laboratory should result from well-defined systems whose properties can be correlated to those in the environment, thereby enabling extrapolation. Mechanistic studies should be conducted on phenomena involved in toxicity, transformation, and transport, coupled with an understanding of key parameters such as nutrients, heavy metals, habitats, temperature, and pH. These parameters, when measured in the environment and correlated to laboratory data, can be used to predict environmental fate and effects.

PROBABILISTIC EXPOSURE MODELS

Research Need

Research is needed to develop probabilistic-based exposure concentration and food-chain models.

Issue(s) Addressed

The research has application to all situations that require assessment of exposure and dose of toxic chemicals.

Justification for Research

The risk presented by a chemical combines the joint probabilities of loading magnitudes, transport and transformation patterns, population exposure histories, and biological responses. Individual deterministic simulation models exist (or are being developed) to address each of these subjects. Risk cannot be easily or accurately estimated, however, without accurate and efficient probability-based simulation techniques. The result of not doing this research would be to maintain reliance on design conditions of unknown risk that may overestimate or underestimate biological effects.

Currently used models do not yield a probability distribution of exposure concentrations for a given problem context. Rather, a point estimate of concentration is determined, possibly with an assessment of the degree of uncertainty associated with that estimate. This information may be used to project exposure probability, but it does not accurately reflect the statistical nature of the parameters controlling the concentration. For example, the probability distribution of a substance in a stream will depend on the probability distribution of flow and the probability distribution of loading, as well as the probability distributions of a host of other processes of lesser importance.

Statistical techniques are available with which to develop models that compute the probability distribution of concentration from the distributions of input parameters. These techniques tend to be mathematically rigorous; as a result, substantial time and effort is required to use these techniques to establish useful models. The advantage of such models is that they can be used with a probability of response to establish a single probability of risk. Without the models, the probability of risk reflects only a subset of the environmental- and chemical-specific conditions that may exist.

One important application of probability models is that they provide a way to perform large-scale simulations. For example, U.S. surface water concentrations can be predicted by using these methods. Another advantage is that the model improves with further understanding of parameter ranges.

Research Plan

1. Develop statistical modeling frameworks capable of considering the probability distributions of forcing functions and model parameters (direct analytical solution, numerical solution, and Monte Carlo simulations).
2. Develop the probabilistic data base for model coefficients and parameters, including covariance among variables.
3. Develop efficient distribution "sampling" techniques to conduct Monte Carlo simulations with dynamic models.

MULTIMEDIA TRANSPORT MODELS

Research Need

Traditional analyses have approached the environmental fate of a toxicant in an independent, decoupled fashion, ignoring intermedia transfer and interactions. This approach has often led to solving a problem in one medium only to transfer the problem to another. Methods are needed to conduct multimedia analyses to apportion the risk by pathway so that more targeted control strategies can be developed.

Issue(s) Addressed

These models will be useful in addressing many current and emerging environmental issues, such as incineration of municipal wastes, atmospheric deposition of organics and metals, landspreading of sludge, volatilization of organics from waste sites, etc.

Justification for Research

Without such methods we will continue to be hampered in our ability to address cross-media issues and to fully evaluate the risks posed by alternative risk-management strategies. This will inevitably lead to selection of risk-management strategies that may merely transfer risk and provide little actual overall risk reduction.

Research Plan

Given the primitive state of multimedia modeling, the most urgent research need is the synthesis and application of such models using already well established single-component models. Specific issues that would be addressed include:

1. the scale of analysis that renders multimedia models useful;
2. the development of fully coupled models, i.e., air-water-soil-plant with feedback loops; and
3. methods to validate these models.

LINKAGE OF EXPOSURE AND EFFECTS MODELS

Research Need

Research should be conducted to explore the most useful and efficient methods of linking exposure and effects models.

Issue(s) Addressed

The linkage of exposure and effects models will add significantly to the ability to make environmental risk assessments for less-than-complete data bases.

Justification for Research

Predicting the biological effects of variable exposure concentrations cannot accurately be accomplished with simple ratios of exposure concentrations to static toxicological effects concentrations. More accurate estimates of risk under realistic environmental conditions can be expected by linking models that predict temporally and spatially variable concentrations with models that predict uptake and effects by using life history, feeding, and perhaps avoidance data as an intermediary. The result of not doing this research would be uncertain calculations of risk under field conditions.

Research Plan

Research on the life histories and feeding behavior of important species should help quantify the probability of an organism being present in different environmental compartments subject to varying degrees of contamination. Software to efficiently combine the variable aquatic concentrations with behavior patterns to give variable exposure concentrations for use in statistically based effects models must be developed. Such software may provide for feedback of information if biological effects are such that can alter aquatic concentrations.

DEVELOPMENT OF EXPERT SYSTEMS FOR ENVIRONMENTAL RISK ASSESSMENT

Research Need

To help make complex loading, exposure, and effects models and data bases accessible and efficient for users, user interfaces including expert systems must be designed, tested, and implemented either separately or in integrated decision support systems.

Issue(s) Addressed

Such user interfaces should aid all exposure, hazard, and risk analyses. This would be particularly helpful for conducting many rapid environmental risk assessment analyses.

Justification for Research

The two main benefits of this research would be to make the user more efficient and more accurate in estimating the potential effects of various chemicals and management options. Efficiency would be achieved by automating many of the time-consuming tasks a user faces in locating and reducing data into proper form for model input. This efficiency would free the user to investigate and explore more alternatives, and to think and learn more about the problem being addressed (as opposed to thinking about the mechanics of computers and data bases). Expert systems would advise the user about selecting the proper model options and values for the coefficients.

Not developing good user interaction software would decrease the utility of the new exposure and effects models and data bases being developed. In particular, integrated risk analyses would be rendered cumbersome and costly. Many potential analyses would not be attempted because of time and resource constraints.

Research Plan

A clear, consistent style of menus, commands, and graphics should be designed and tested with several models and users. Technical dictionaries and help files should be built and referenced to the input variables of several "supported" models. Expert advisors should be constructed in several technical disciplines. Data base interaction software should be refined to achieve ease of use and efficiency across several data bases. A consistent geographical information system should be adopted and linked to national and regional data bases and mapping and plotting routines.

RELATIONSHIPS BETWEEN BODY BURDEN AND TOXIC EFFECTS

Research Need

There is a pressing need for quantification of the relationship between body burden (or some other biochemical parameter) and toxic effect.

Issue(s) Addressed

This research will address the issue of the relationship between exposure history and the risk or extent of injury to a population. In so doing, this research encompasses a variety of environmental issues concerned with risk assessment in aquatic systems.

Justification for Research

The response of a population to a toxic substance is governed by the total dose received and the rate at which the dose is received. In aquatic toxicology, dose is not generally measured. Instead, the response of the population is related to the concentration of chemical to which the population is exposed. Use of this relationship in risk assessment requires two major assumptions:

1. The exposure history of the population at risk is identical to that used to establish the concentration-response relationship.
2. The metabolic parameters controlling uptake and loss of the toxic substance are the same for the population at risk and the population used to establish the concentration-response relationship.

In most problem contexts, source and environment variability cause the exposure concentration to be some function of space and time. This variability, coupled with bioenergetic variability and life history characteristics, may significantly affect the dose received and thus invalidate the assumptions listed above. As a result, the validity of the risk assessment is questionable.

Research to quantify a body burden-toxicity relationship provides the benefit of eliminating the critical assumptions described above. Such a relationship permits the refinement of risk assessment to include direct modeling of toxic substance uptake by a population for any exposure history, and the computation of risk based on the comparison of the amount of toxicant that the population has taken in (dose) and the probability of response.

Research Plan

1. Methods development:
   a. Establish appropriate internal measurements that correlate with toxicity (e.g., body burden, specific tissue concentration, biochemical measure such as acetylcholinesterase inhibition) for various classes of substances.
   b. Develop procedures for testing.
2. Develop pharmacokinetic models to predict the levels of appropriate internal measurements in relation to exposure concentrations and environmental conditions.
3. Combined laboratory and modeling studies to evaluate the approach.
4. Validate the approach through field testing.

TOXICITY OF METABOLITES

Research Need

Metabolic intermediates and degradation products of toxicants are sometimes more toxic than the parent compound. It has long been recognized that induction of cancerous tumors by somatic mutation can be a consequence of this detoxification response in organisms. Assessment tools are needed to carefully evaluate the toxicological consequences of chemical fate.

Issue(s) Addressed

The presence of metabolic intermediates and degradation products is ubiquitous. For example, 46 potential or known carcinogenic/toxic organics have been found in drinking water of communities along the Mississippi River. Toxicology of metabolites and degradation products in groundwater, fugitive emissions, abandoned waste sites, and some industrial and domestic sludges and effluents is generally unknown.

Justification for Research

With a better understanding of metabolite toxicity, predictable responses of the detoxification/activation systems of organisms may be realized. This is of major importance from an epidemiological or community health perspective. The persistent question of "How clean is clean?" may only be answered after questions on toxicant exposure and differences in xenobiotic metabolism can be identified. Major benefits can be realized in ensuring the safety of drinking water sources, particularly threatened aquifers. Postclosure care documentation of decontaminated RCRA/CERCLA (SARA) sites may be more meaningful in evaluating the potential future usage of such sites.

Research Plan

Three specific assay tools are currently in an embryonic stage of development, tools which should be further expanded:

1. The bacterial assay system developed by Bruce Ames and his associates which uses *Salmonella typhimurium* is an example of an effective screening tool for mutagenicity. It has limitations, of course, and other assays are also required in order to make proper risk assessments. A more sensitive and specific assay, a 32p postlabelling technique, is still needed for future studies on health effects.
2. Another risk assessment tool is the response of detoxification/activation enzyme systems of invertebrates to organic pollutants and xenobiotics. The Cytochrome P-450 mixed-function oxidase (MFO) system is a universally-distributed system involved in the metabolism of xenobiotics taken up into the tissues of organisms and of certain endogenous compounds such as steroid hormones and fatty acids. The MFO system has been extensively investigated in the past few decades, although until recently almost exclusively in mammalians and prokaryotic systems. In recent years the MFO system of lower vertebrates, such as fish, has received a great deal of attention.
3. Because major biochemical differences have been found to exist between organisms from different phyla it is quite possible that fundamental differences in xenobiotic metabolism could also exist. Additional funding is needed to expand this and other short-term tests into a more comprehensive interlaboratory testing program. With proper guidelines, such tests can become effective management tools for risk assessment.

TOXICITY OF COMPLEX MIXTURES

Research Need

Research is needed in the redesign and validation of new toxicity assays that can handle the difficult problem of toxicity of complex mixtures. Methods developed to date reflect usually only single toxicant/single organism exposure event. Rarely are organisms subjected to complex toxicants.

Issue(s) Addressed

Complex mixtures of toxic materials are the norm in most RCRA and CERCLA/SARA sites. The successful decontamination of such sites is dependent upon the understanding of how individual components of known toxicity will behave as a mixture when such complex mixtures are incinerated, solidified, biodegraded, or simply stored in a vault system. Additionally, the relative toxicity of volatile and fugitive emissions from such sites with regards to human toxicology is unknown. Finally, understanding the effect of complex mixture toxicity on aquatic biota after publicly owned treatment works (POTW) discharge is a high priority for cities and municipalities.

Justification for Research

Significant expenditures have been and will be directed toward the evaluation of hazardous waste sites and locations where specific recommendations will be made regarding site remediation or containment. Selection of specific technologies must not only be cost-effective, but must also pose minimal environmental risk to the general public. Documentation of the toxicological consequences of specific technologies for specific sites would be an important management tool in achieving the safe, expeditious closure of the greatest number of sites.

Without acceptable assays, important environmental health questions cannot be answered. Human exposure to potential toxicants is almost always multiple. Thus, the biological activity of these mixtures on human populations cannot be ascertained. For example, complex mixtures in the form of POTW effluents are an active concern of regulatory agencies. Further understanding of toxic interactions is key to determining which chemicals (and amounts) pose a threat to aquatic biota.

Research Plan

1. Interlaboratory research must be conducted and standardized in dose-response relationships for toxic mixtures. This should be followed by comprehensive studies on species comparisons with the clear focus of establishing some threshold effect concentration.
2. Models predicting interactions and effects of multiple toxicant exposure can only be realized when extensive data sets can be generated on the identity and toxicological nature of hazardous chemical mixture and an epidemiological studies of exposure to these mixtures.
3. More sentinel or indicator species that can be utilized *in situ* (either naturally occurring or introduced) are needed to identify sites where ecotoxic effects exist.

TOXICANT EFFECTS ON ECOSYSTEMS

Research Need

Long-term field studies are needed to quantify and better characterize the status of important ecosystems and to establish a baseline of information from which trend analyses can be carried out.

Issue(s) Addressed

We need to be able to detect and measure human-induced changes in ecosystems, classify systems by their vulnerability to stress, understand the way they behave in response to multiple impacts, and will begin to define protective criteria for dealing with cumulative contamination.

Justification for Research

Studies of this type will improve our knowledge of how ecosystems respond to stress (chemical/biological/physical) and provide decision-makers with the requisite information to assess the need for remedial actions and to address emerging problems. The result of not doing this research would be to overlook or not be able to adequately address large-scale or long-term ecological impacts.

Research Plan

Select several significant ecosystems in which integrated environmental assessments can be done on a regional scale to assess long-term effects on biodiversity, primary and secondary productivity, and other ecological endpoints. These ecosystems would be the focus of both short-term and long-term research studies; over time, they would provide information on a regional scale on such issues as chronic and cumulative degradation and the interaction between chemical contamination and other kinds of environmental impacts.

APPENDIX E:
GLOSSARY

APPENDIX E: GLOSSARY

Risk: The chance of a prescribed undesired effect, such as injury, disease, or death, resulting from human actions or a natural catastrophe.

Risk Assessment: A set of formal scientific methods for estimating the probabilities and magnitudes of undesired effects resulting from the release of chemicals, other human actions, or natural catastrophes. Risk assessment includes quantitative determination of both exposure and effects.

Exposure: The process by which a chemical is delivered to an organism, resulting in a dose (the amount of a chemical either in the organism as a whole or in a target tissue). Exposure is a result of the concentration and form of a chemical in the environment, coupled with the presence of the organism.

Exposure Assessment: The process of estimating the dose received by an organism population, or ecosystem. It may be prospective, in which case estimates of the chemical concentrations and forms in various media or habitats are combined with estimates of the organism's behavior to predict dose. It may also be retrospective, in which case dose is estimated from body burdens of the chemical or changes in the organism caused by the chemical (biomarkers).

Effects Endpoint: The undesired effect whose probability of occurrence is estimated in a risk assessment. Examples include extinction of an endangered species, eutrophication of a lake, or the cost to the timber industry of air pollution.

Test Endpoint: The expression of the results of a toxicity test. It may be a single number (LC50), a function (probit, probit plane, logit), or simply a tabular, graphical, or verbal presentation of observed effects.

Uncertainty: Uncertainty can result from lack of knowledge, inherent variability (stochasticity), or imprecise measurements. It causes data to be interpreted as a distribution of values rather than a single value. It causes decision-makers to either consider the possibility that effects may be greater or less than expected or to conduct additional research and testing in order to reduce uncertainty.

Probability: The likelihood that a parameter will assume a particular state or value. It is a numeric expression of uncertainty (e.g., the probability that exposure to a toxic effluent will cause a fish kill is one in one hundred [0.01]).

Environmental Risk Assessment: Those risk assessments that address events in the environment including release of pollutants, physical modification of the environment, and natural disasters. For the purposes of this document, the phrases "environmental risk assessment" and "ecological risk assessment" are viewed to be synonymous. The issue of human health risk assessment research needs is not addressed directly.

Ecological Risk Assessment: Those environmental risk assessments that address effects on plants, animals, and ecosystems.

Hazard: An action or condition that has the potential to cause an undesired effect. The nature of the hazard might include death, cancer induction, sterility, extinction of a population, or eutrophication of a lake.

Hazard Assessment: A process designed to determine whether the release of a chemical constitutes a hazard. It involves an interactive process of testing followed by a judgment as to whether (1) the expected environmental concentration is clearly higher than the lowest test endpoint, (2) the expected environmental concentration is clearly lower than the lowest test endpoint, or (3) no clear judgment can be made and a higher tier of testing must be performed. This definition is traditional in ecological toxicology. In human health risk assessment, hazard assessment refers to the determination of inherent toxicity.

APPENDIX F:
NAMES AND ADDRESSES
OF WORKSHOP PARTICIPANTS

APPENDIX F: NAMES AND ADDRESSES OF WORKSHOP PARTICIPANTS

Dr. William J. Adams
Monsanto Company
800 N. Lindbergh Blvd. (NIB)
St. Louis, MO 63167
(314) 694-4407

Mr. Robert Ambrose
Environmental Research Laboratory
U.S. EPA
College Station Road
Athens, Georgia 30613
(404) 546-3546

Dr. William E. Bishop
The Procter and Gamble Company
5299 Spring Grove Avenue
Cincinnati, OH 45217
(513) 627-6145

Dr. John Connolly
Manhattan College
Environmental Engineering and Science
Bronx, NY 10471
(212) 920-0276

Dr. Gary W. Dickson
CIBA-GEIGY
P.O. Box 18300
Greensboro, NC 27419
(919) 292-7100

Dr. Kenneth L. Dickson
North Texas State University
P.O. Box 13078
North Texas Station
Denton, TX 76201
(817) 565-2694

Dr. Richard T. DiGiulio
School of Forestry and Environmental Studies
Duke University
Durham, NC 27706
(919) 684-6090

Mr. Donald J. Ehreth
P.O. Box 1549
6850 Versar Center
Springfield, VA 22151
(703) 750-3000

Dr. James A. Fava
Battelle Columbus Division
505 King Avenue
Columbus, OH 43201
(614) 424-6311

Dr. James Gagne
American Cyanamid Company
P.O. Box 400
Princeton, NJ 08540
(609) 799-0400

Dr. James W. Gillett
Department of Natural Resources
114 Fernow Hall
Cornell University
Ithaca, NY 14853-3001
(607) 255-2163

Dr. Robert Graney
Hoechst-Roussel
Agri-Vet Company
202-206 N
Summerville, NJ 08876
(201) 231-3025

Dr. Robert Huggett
Virginia Institute of Marine Science
College of William and Mary
Glouster Point, VA 23062
(804) 642-7236

Dr. Ronald Kendall
Institute of Wildlife Toxicology
Western Washington State University
Bellingham, WA 98225
(206) 676-3972

Dr. Richard Kimerle
Monsanto Co (U4E)
800 N. Lindbergh Blvd.
St. Louis, MO 63167
(314) 694-3286

Dr. Wayne Landis
USA Aberdeen Proving Grounds
Chemical R & D Center
ORSMC-CLD-T(A)
Aberdeen Proving Grounds, MD 21010
(301) 671-2764/3602

Dr. Robert Larson
Procter and Gamble
5299 Spring Grove Avenue
Cincinnati, OH 45217
(513) 627-6489

Dr. Christopher Lee
Unilever Research
Port Sunlight Laboratory
Quarry Road, East, Bebington
Wirral, Merseyside
England L63 3JW
(051) 645-2000

Dr. Paul Mehrle
U.S. DOI Fish and Wildlife Service
National Fisheries Contaminant Research Center
Route 1
Columbia, MO 65201
(314) 875-5399

Dr. John McCarthy
NACA
1155 15th Street NW
Suite 900
Washington, D.C. 20005
(202) 296-1585

Mr. Rodney Parrish
U.S. EPA
Environmental Research Laboratory
Sabine Island
Gulf Breeze, FL 32561
(904) 932-5311

Dr. Gerald Poje
National Wildlife Federation
1412 16th St. NW
Washington, D.C. 20036
(202) 637-3737

Dr. Ralph Portier
Aquatic and Industrial Toxicology Laboratories
Institute for Environmental Studies
42 Atkinson Hall
Louisiana State University
Baton Rouge, LA 70803
(504) 388-8521

Dr. Robert A. Rapaport
The Environmental Safety Department
Procter and Gamble Company
Ivorydale Technical Center
Room A100D
Cincinnati, OH 45217
(513) 627-5953

Dr. Margaret A. Rostker
Office of Pesticides and Toxic Substances
U.S. EPA
401 M Street SW
Washington, DC 20460
(202) 382-2892

Dr. Thomas Sabourin
Battelle Columbus Division
505 King Avenue
Columbus, Ohio 43201
(614) 424-7180

Mr. Stephen C. Schimmel
U.S. EPA
Environmental Research Laboratory
South Ferry Road
Narragansett, RI 02879
(401) 782-3078

Mr. Randy Scott
Office of Environmental Audit
U.S. Department of Energy
1000 Independence
Washington, D.C. 20585
(202) 586-5605

Dr. Peter Greig-Smith
Minister of Agriculture, Fisheries, and Food
Tolworth Laboratories
Hook Rise
Tolworth
Surbiton
Surrey, United Kingdom KT6-7NS
01-337-6611 x421

Dr. Glenn Suter II
Oak Ridge National Laboratory
P.O. Box X
Oak Ridge, TN 37831
(615) 574-7306

Dr. William H. van der Schalie
U.S. Army
USAMBRDL, Building 568
Fort Detrick
Frederick, MD 21701
(301) 663-2750

Dr. Peter Van Voris
Battelle, Pacific Northwest Laboratories
Battelle Boulevard
P.O. Box 999
Richland, WA 99352
(509) 375-2498

Dr. Barbara Walton
Environmental Sciences Division
Oak Ridge National Laboratory
P.O. Box X
Oak Ridge, TN 37831
(615) 574-7839

Dr. Molly Whitworth
Patuxent Wildlife Research Center
U.S. Fish and Wildlife Service
Laurel, MD 20708
(301) 498-0375

Dr. Bill Williams
United States Environmental Protection Agency
Environmental Research Laboratory
200 S. W. 35th Street
Corvallis, OR 97333
(503) 757-4679

Dr. William P. Wood
U.S. EPA (RD 682)
401 M Street SW
Washington, D.C. 20460
(202) 475-7392

Dr. Armon F. Yanders
University of Missouri
Environmental Trace Substances Research Center
Rt #3
Columbia, Missouri 65203
(314) 882-2151

Dr. Terry F. Yosie
U.S. EPA
401 M Street SW
Room W1145
Mail Stop A 101
Washington, D.C. 20460
(202) 382-4126

Dr. Alvin L. Young
Executive Office of The President
Office of Science and Technology Policy
New Executive Office Building,
Room 5005
Washington, D.C. 20506
(202) 395-3125